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Biedermann et al.

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(54) **POLYAXIAL BONE ANCHORING DEVICE**

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(58) **Field of Classification Search**
CPC combination set(s) only.
See application file for complete search history.

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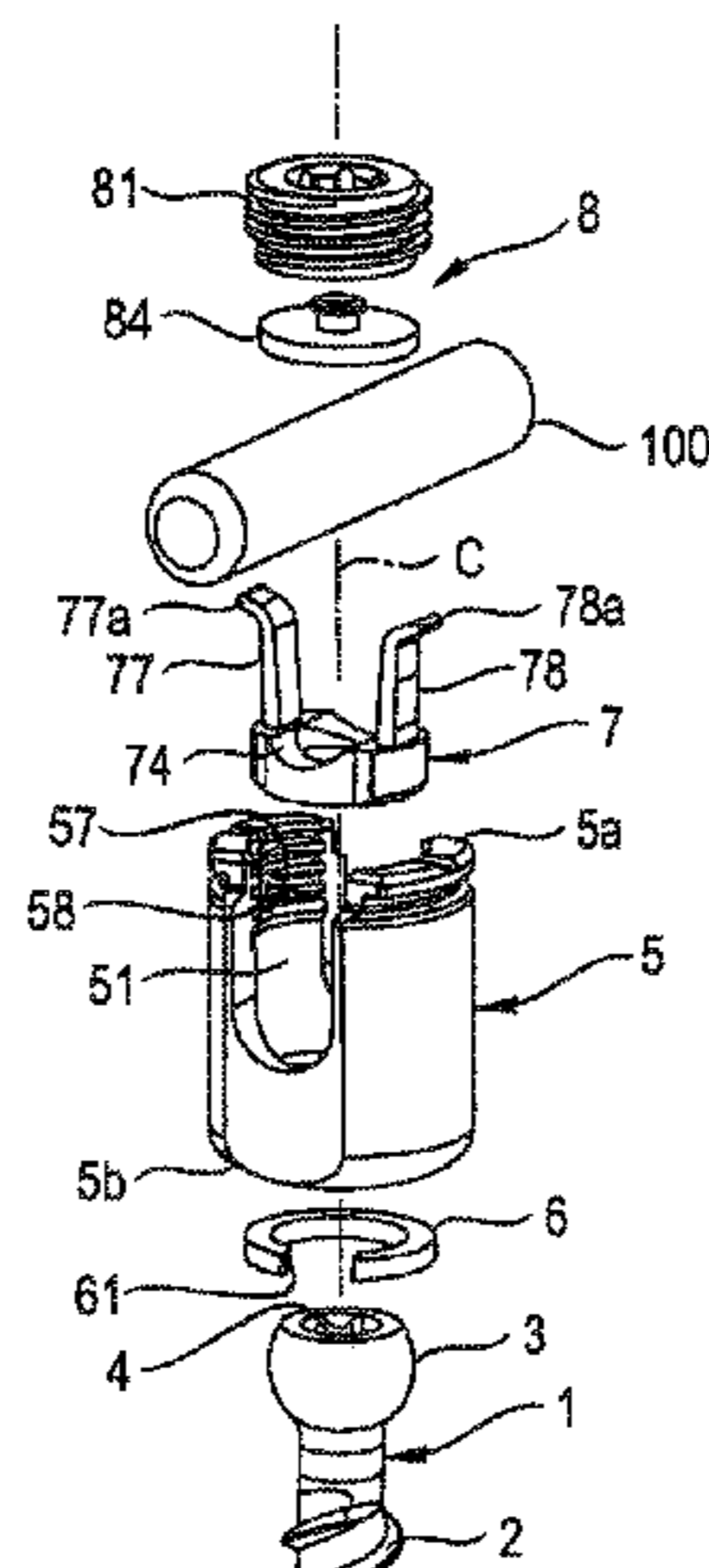
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(57) **ABSTRACT**

A polyaxial bone anchoring device includes a receiving part having a longitudinal axis, a channel for receiving a rod, and an accommodation space for pivotably holding a head of a bone anchoring element, and a pressure member configured to be positioned in the receiving part and to exert pressure onto the head to lock the head in the receiving part. The pressure member includes a pressure exerting surface and a deformable portion having a free end, wherein the deformable portion is configured to assume at least a first configuration and a second configuration. The polyaxial bone anchoring device further includes a locking member configured to be inserted into the channel and to exert a force onto the deformable portion. When the head and the pressure member and the locking member are in the receiving part, the free end of the deformable portion is supported in the receiving part, and the locking member is movable in the channel along the longitudinal direction in such a manner

(Continued)



that the locking member first contacts the deformable portion and exerts a force onto the deformable portion to bring the deformable portion from the first configuration into the second configuration thereby locking the head. Thereafter the locking member comes into contact with the rod and locks the rod.

18 Claims, 8 Drawing Sheets

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(60) Provisional application No. 62/035,666, filed on Aug. 11, 2014.

(51) **Int. Cl.**
A61F 2/08 (2006.01)
A61B 17/70 (2006.01)

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Fig. 1

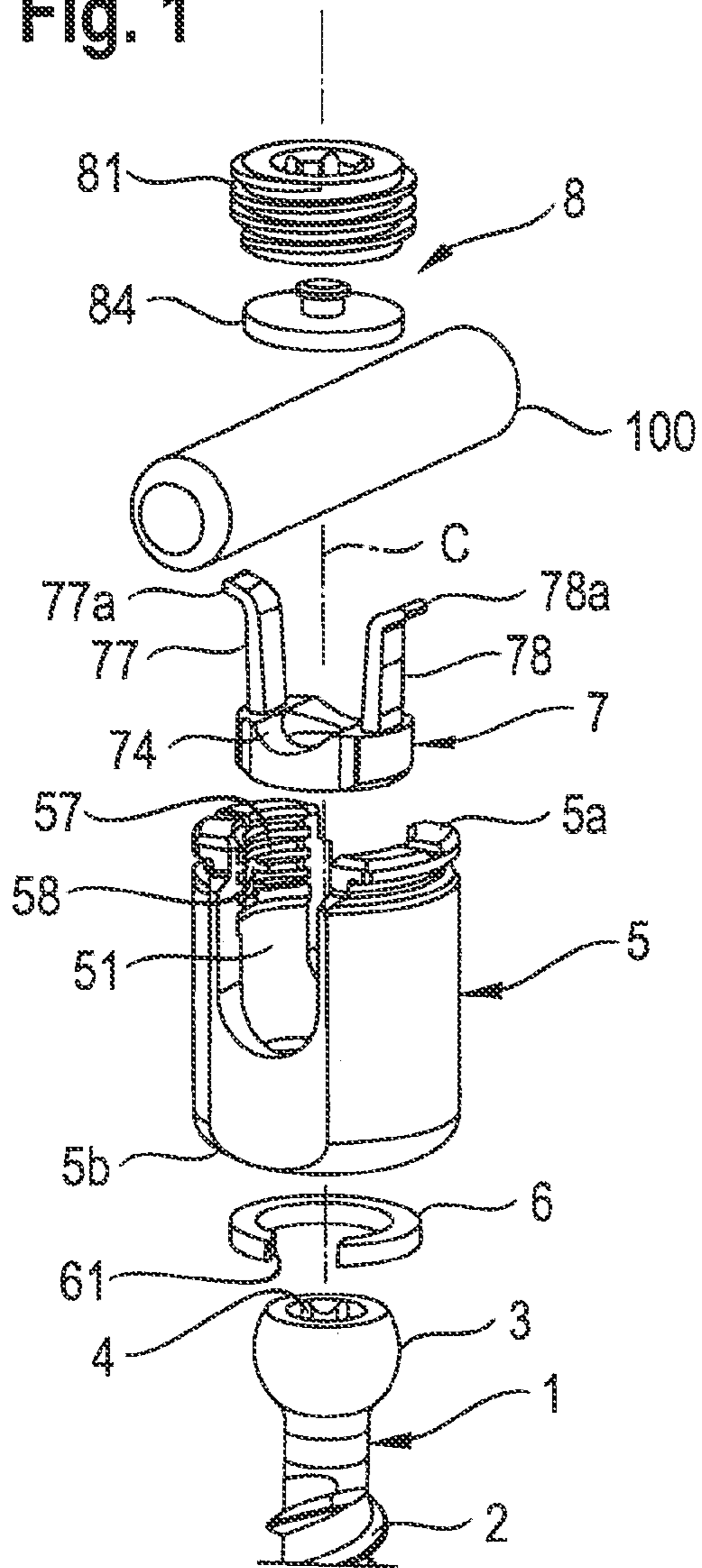


Fig. 2

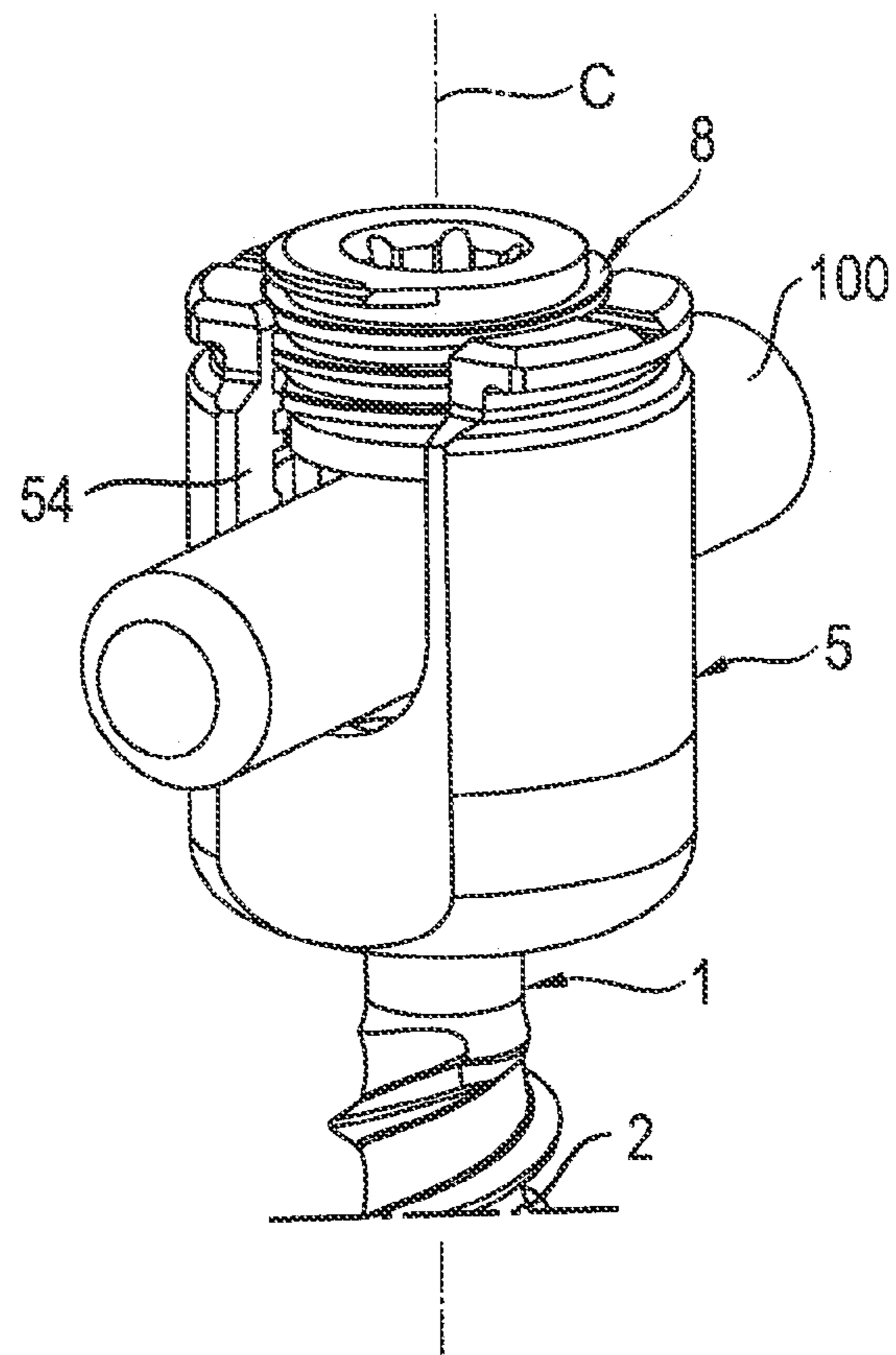


Fig. 3

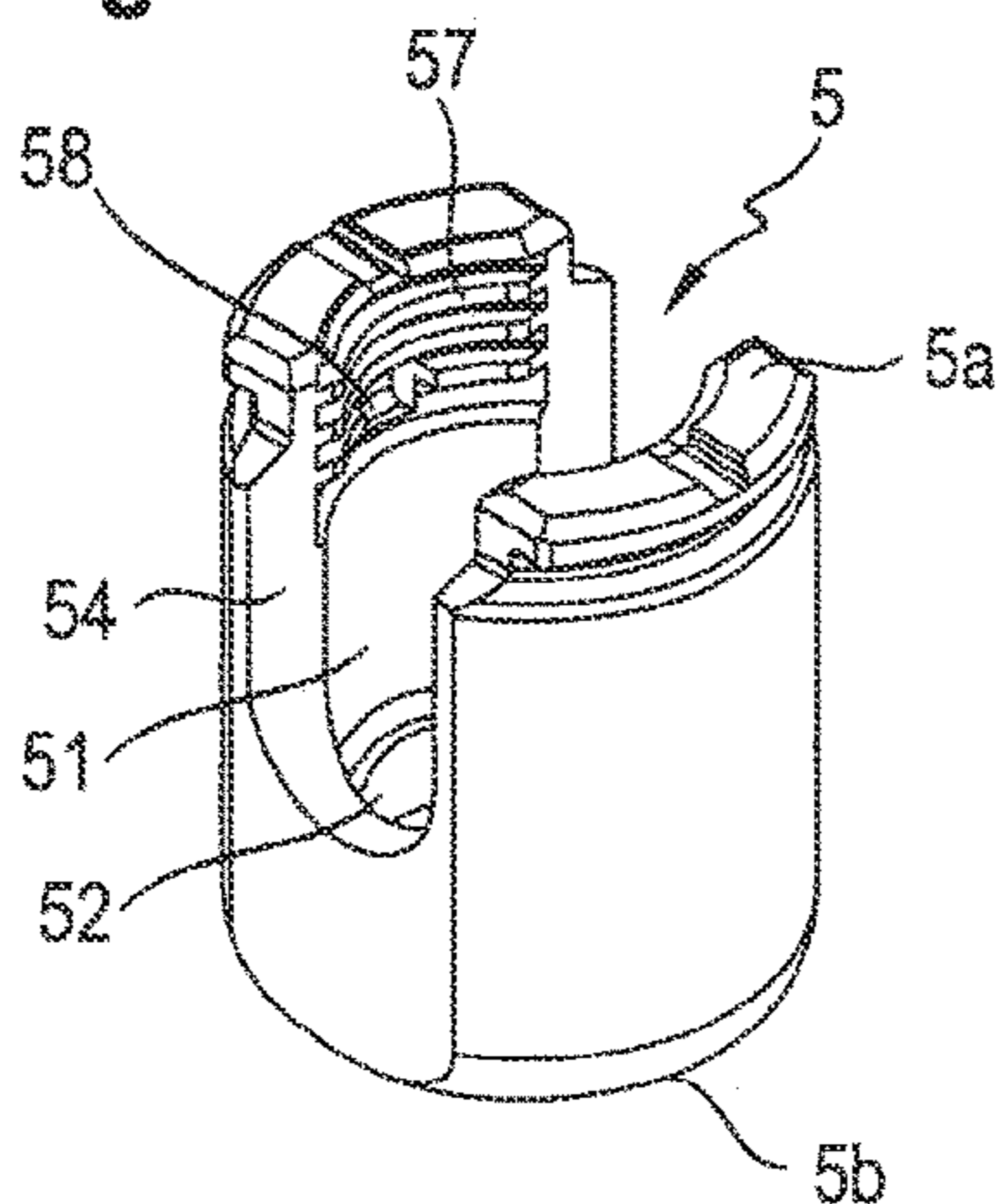


Fig. 4

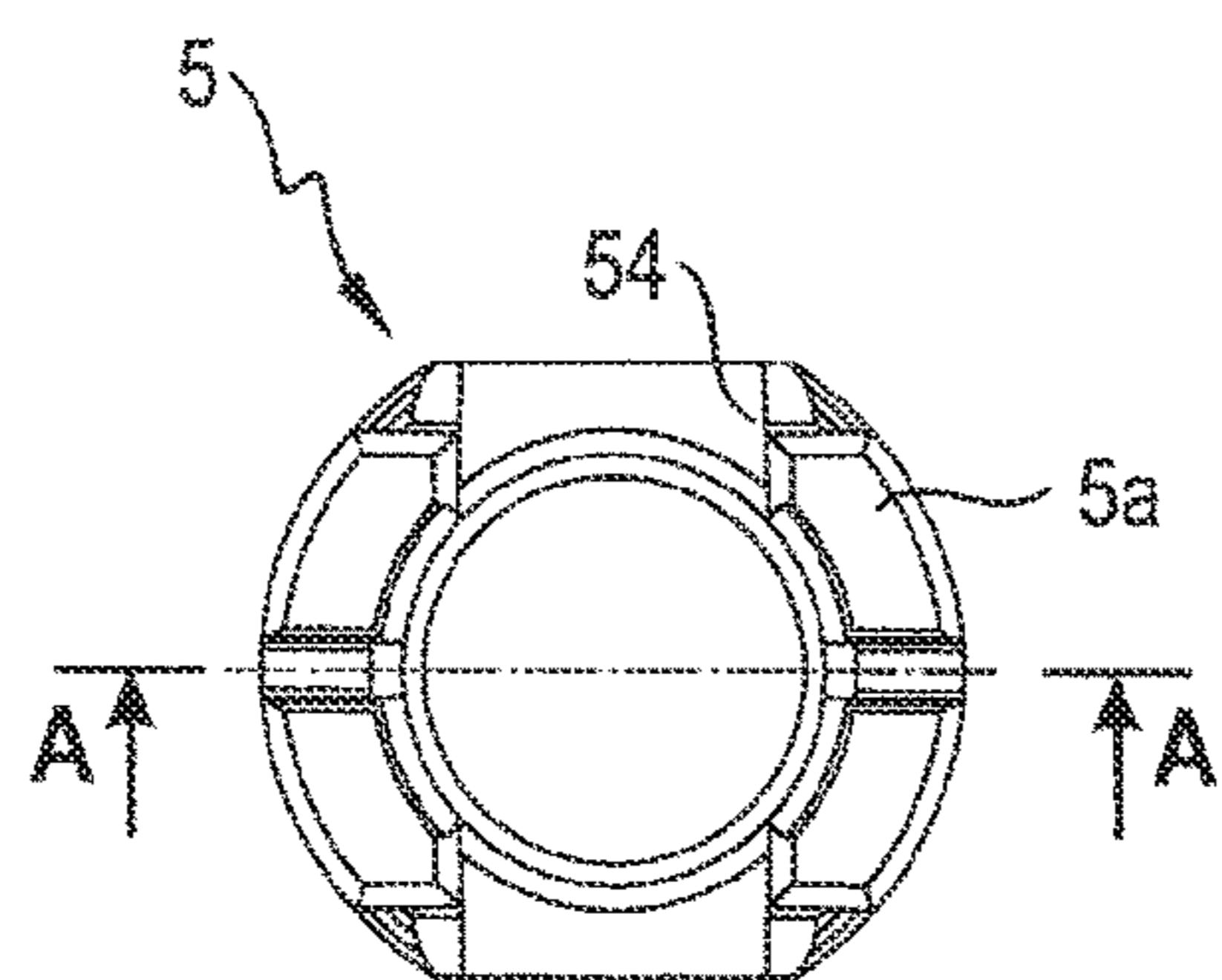
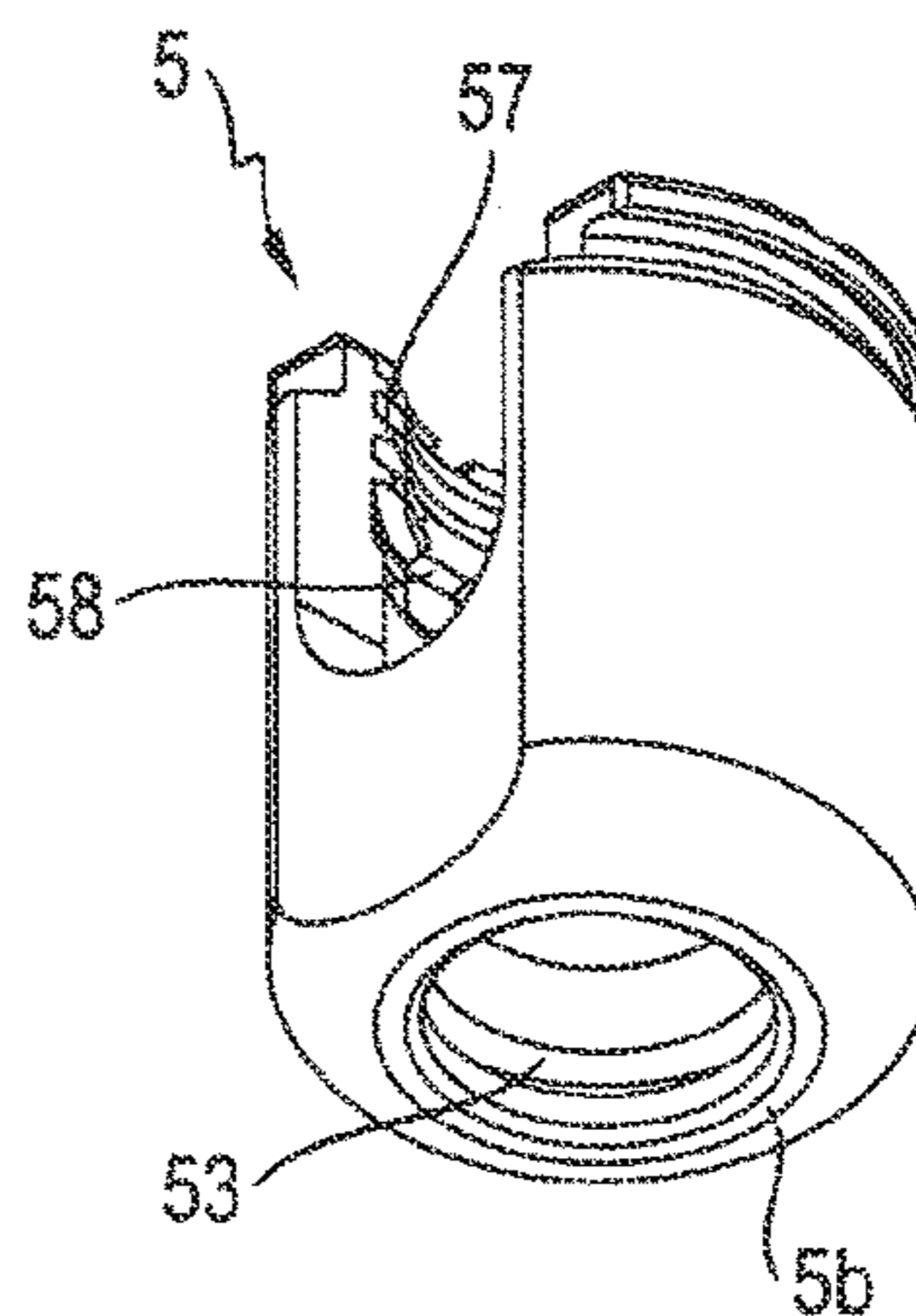


Fig. 5

Fig. 6

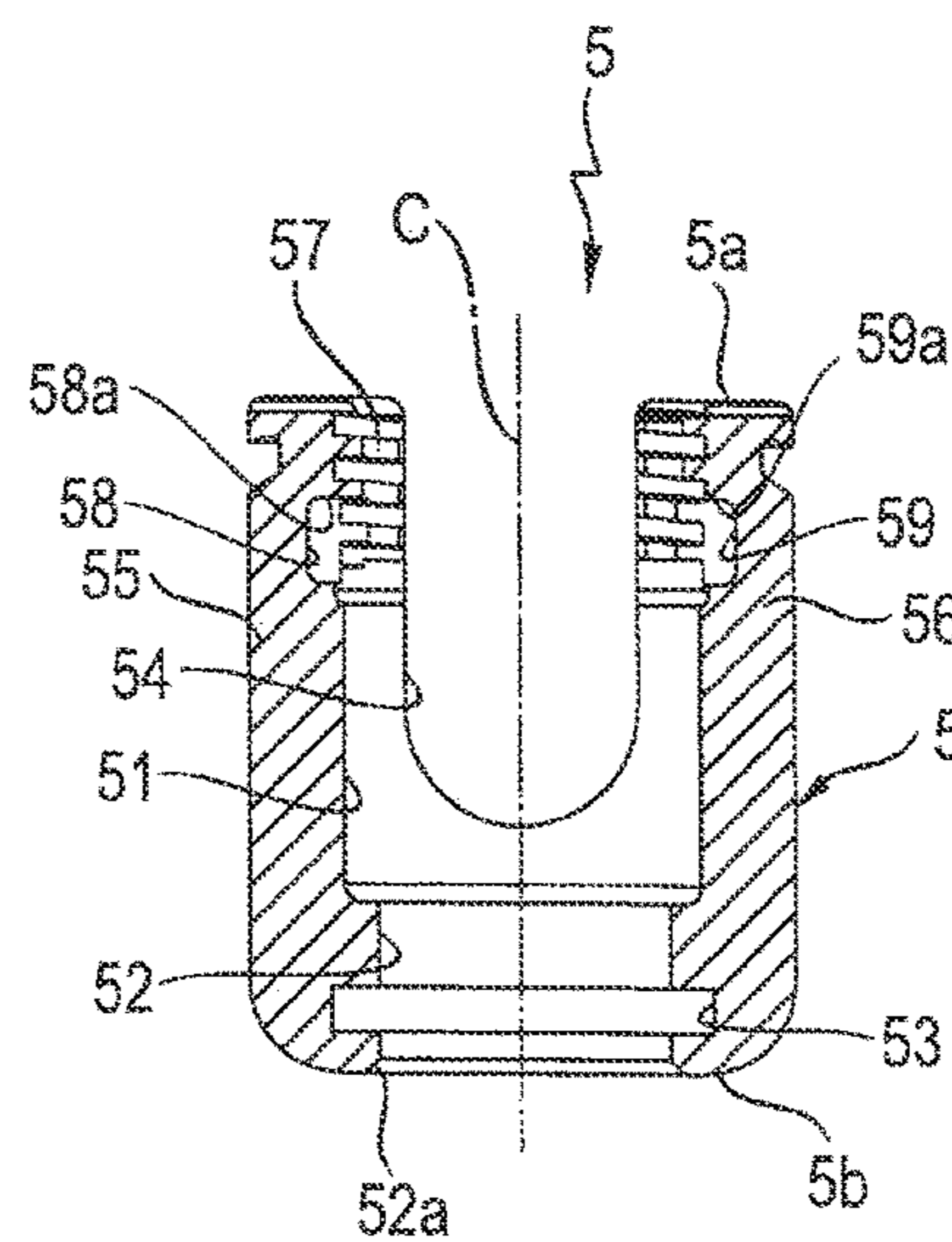


Fig. 7

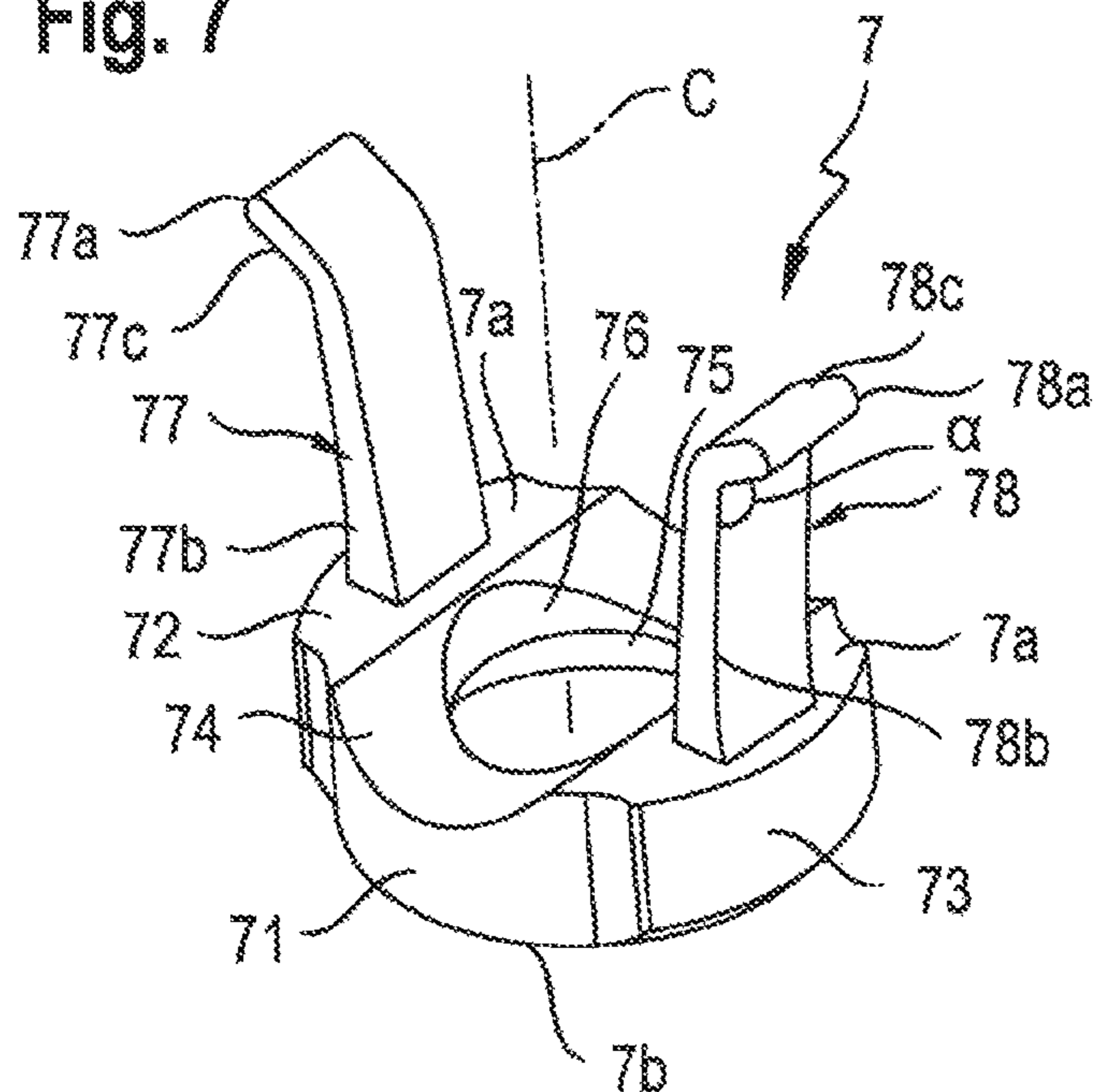


Fig. 8

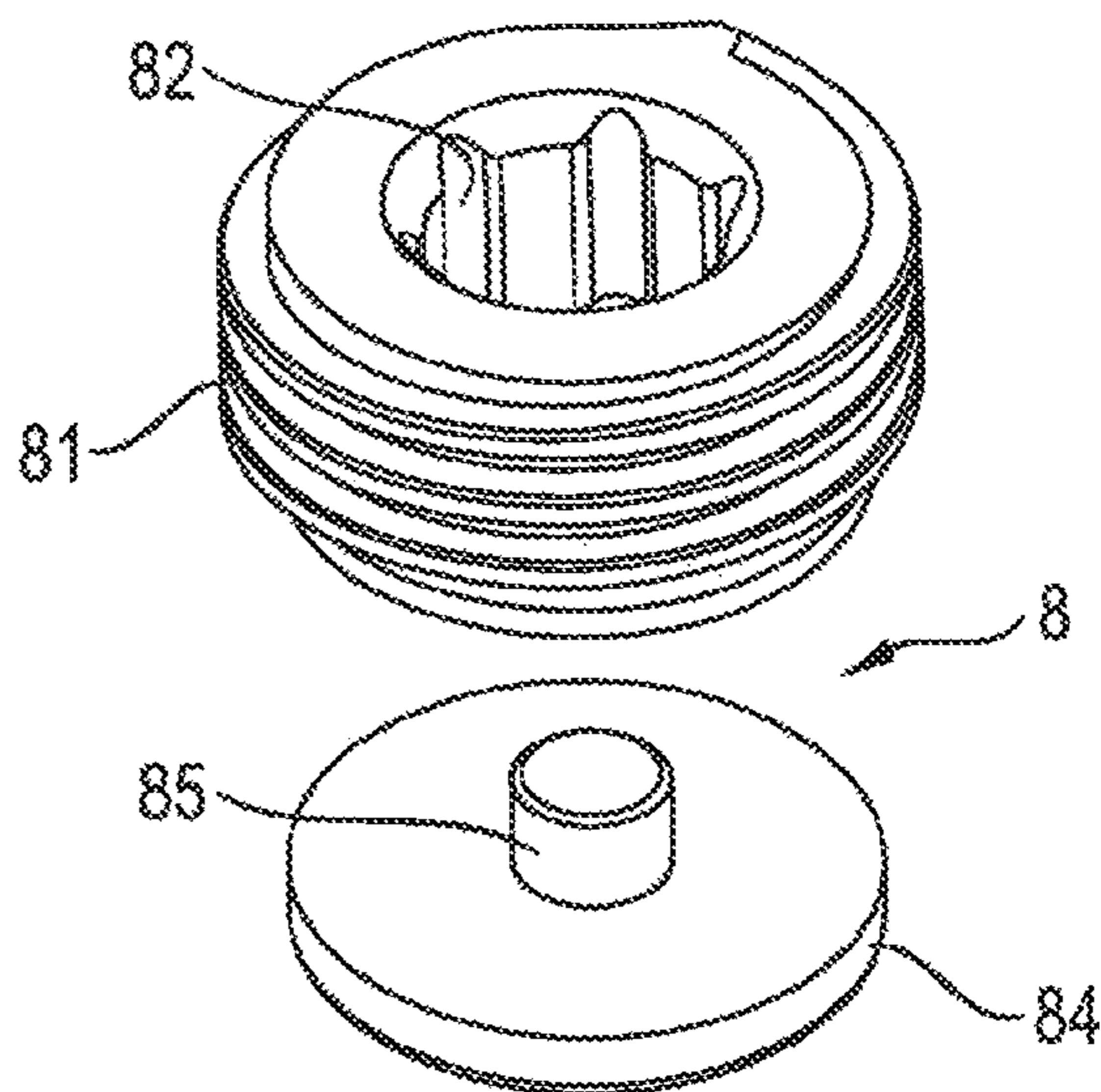
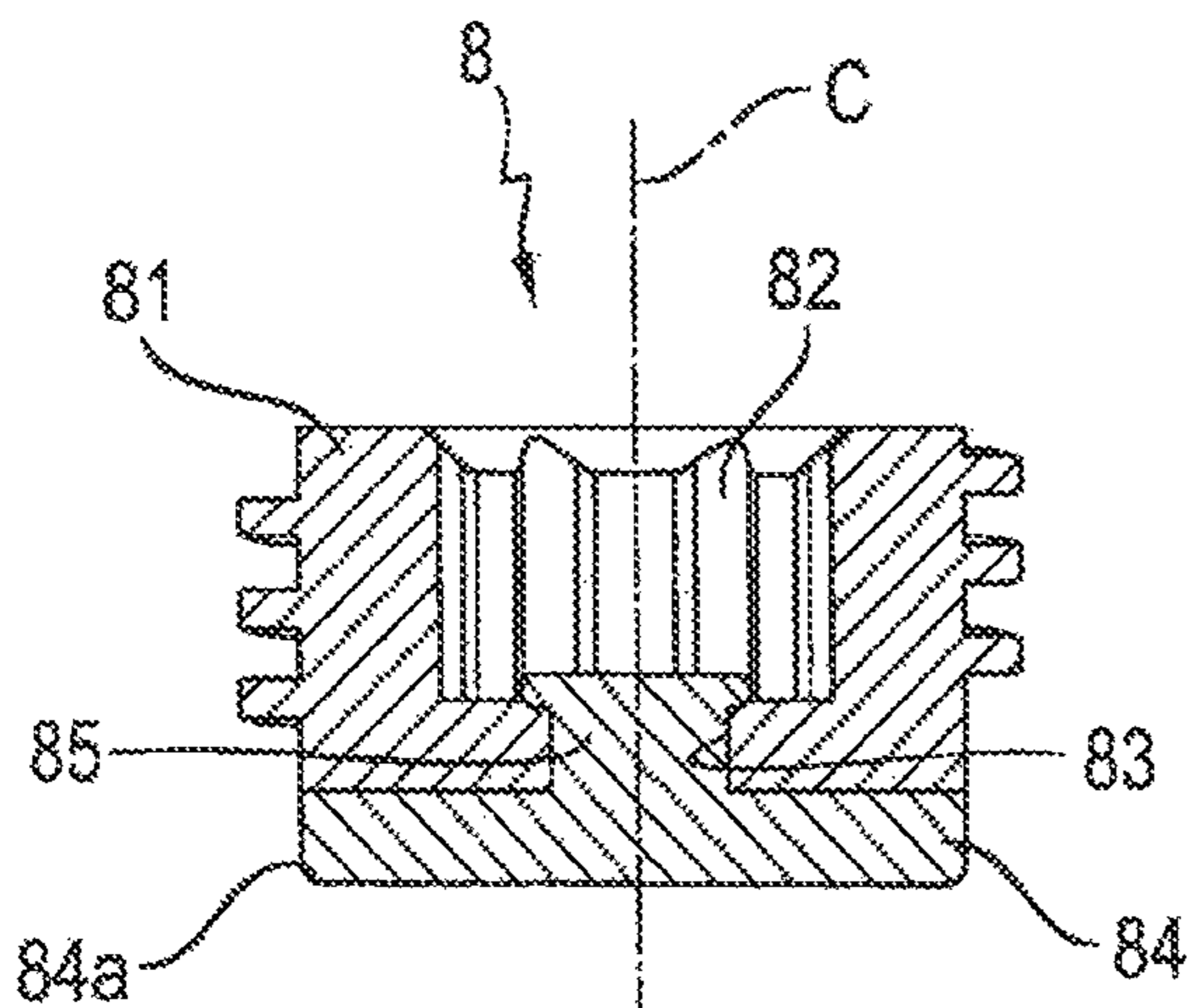


Fig. 9



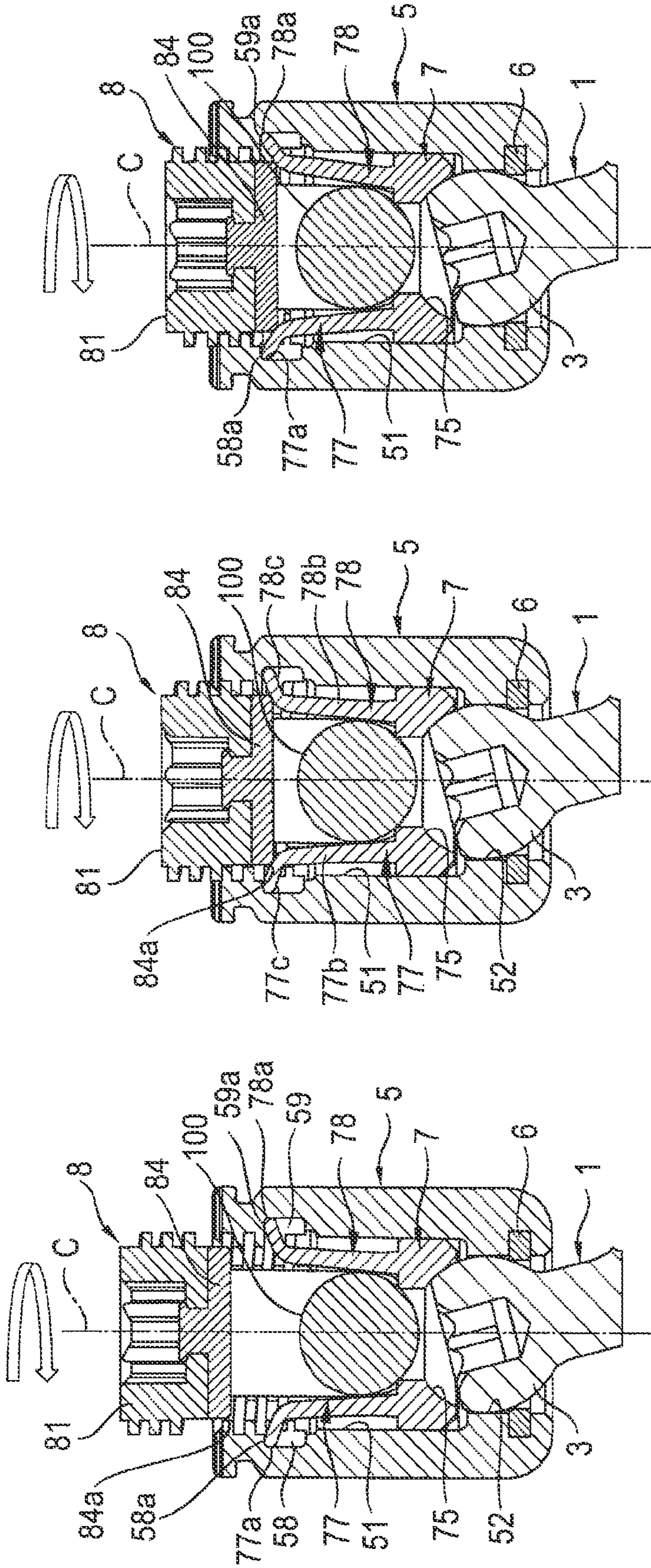


Fig. 10a

Fig. 10b

Fig. 10c

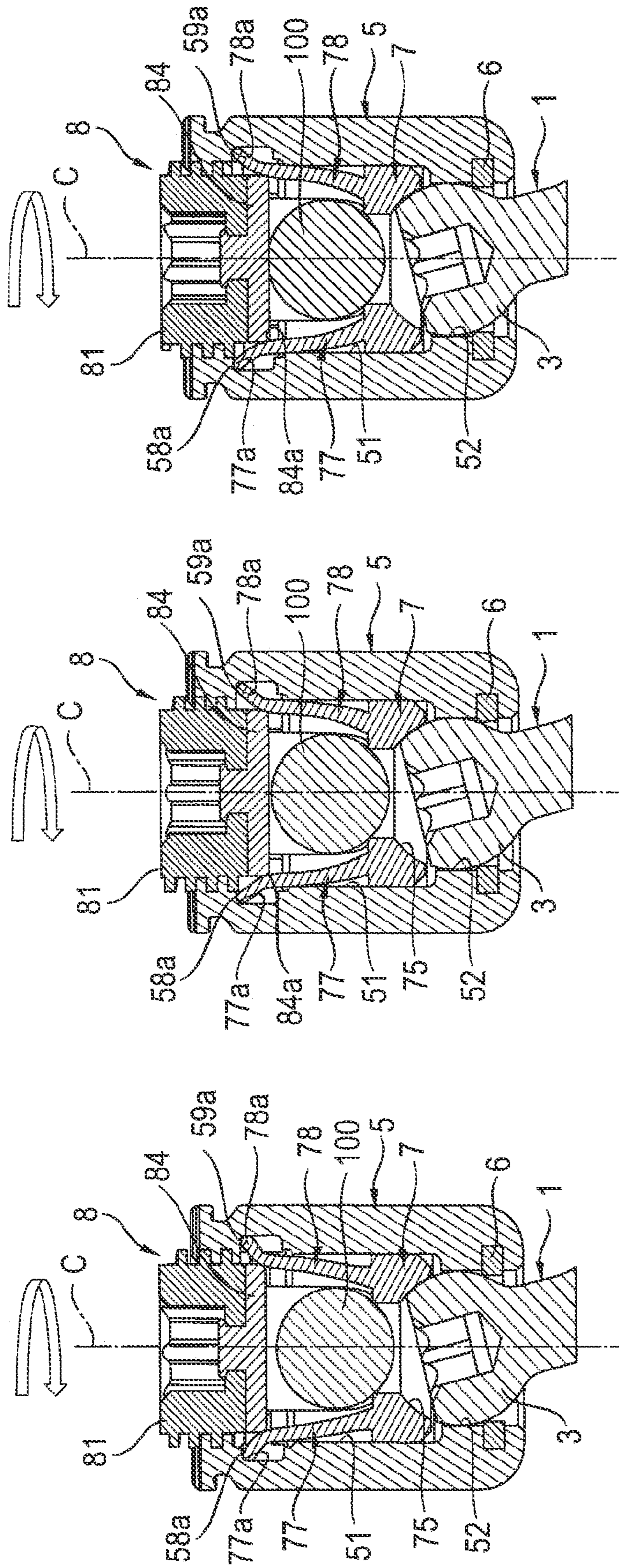


Fig. 10f

Fig. 10e

Fig. 10d

Fig. 11

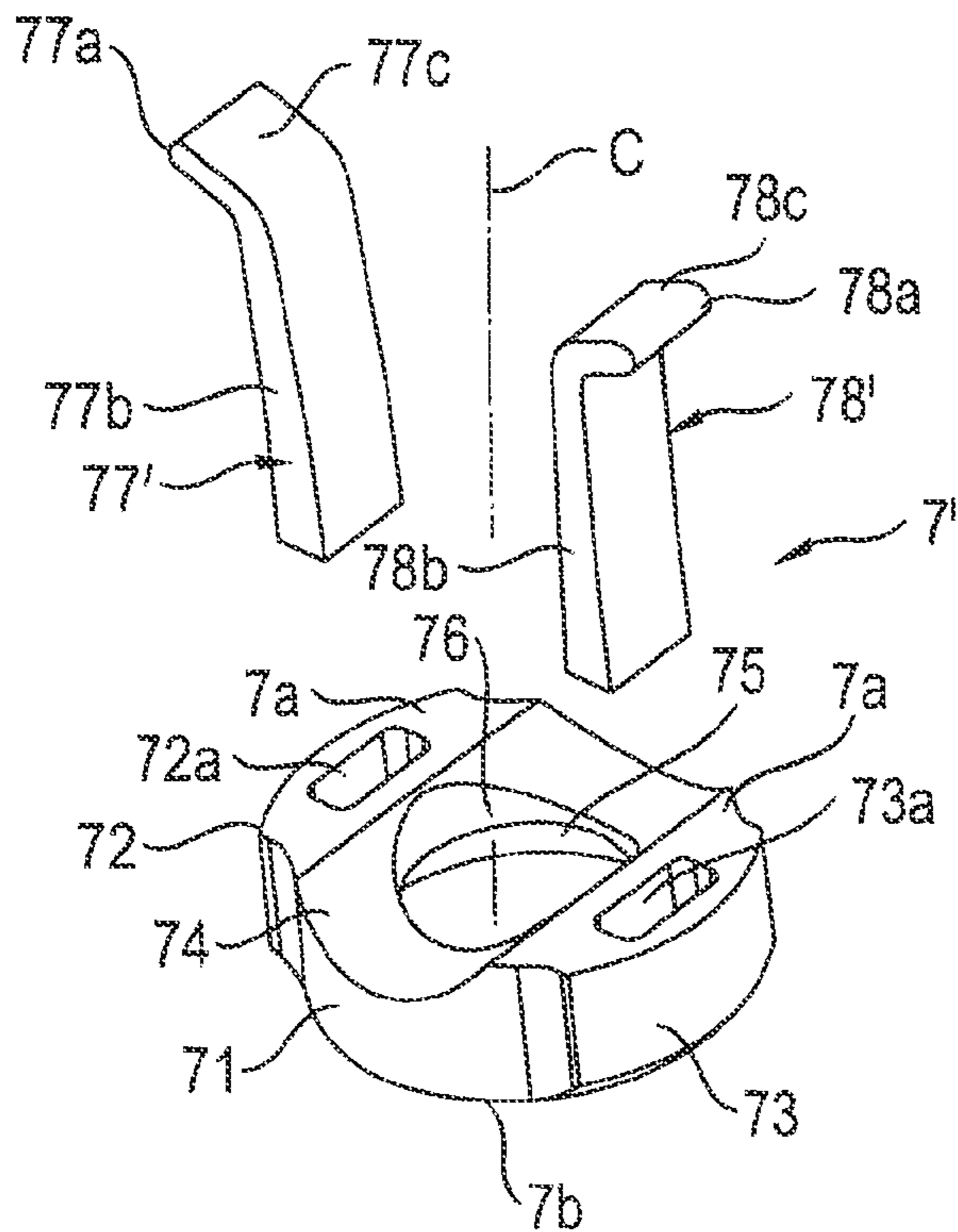


Fig. 12

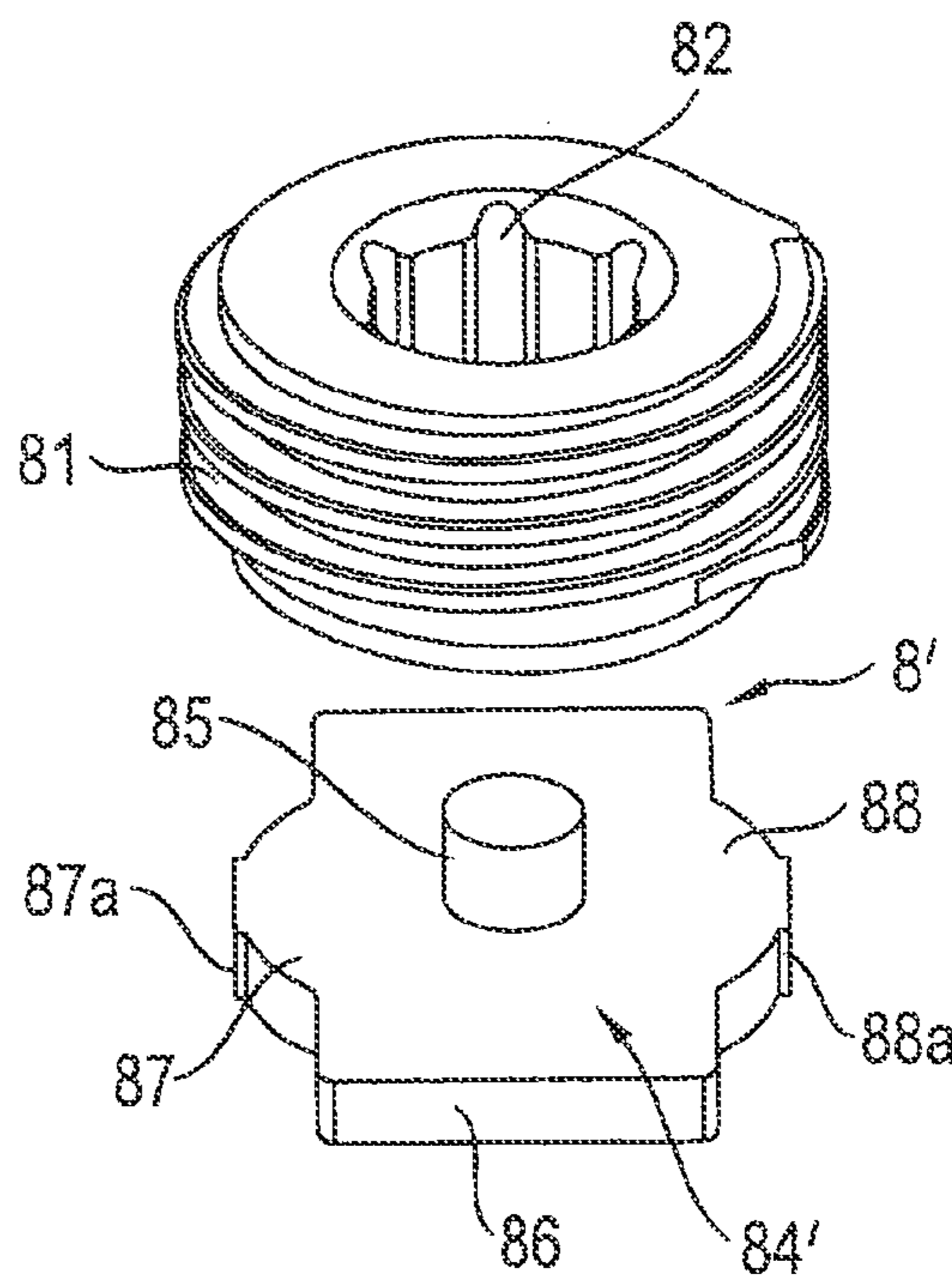


Fig. 13

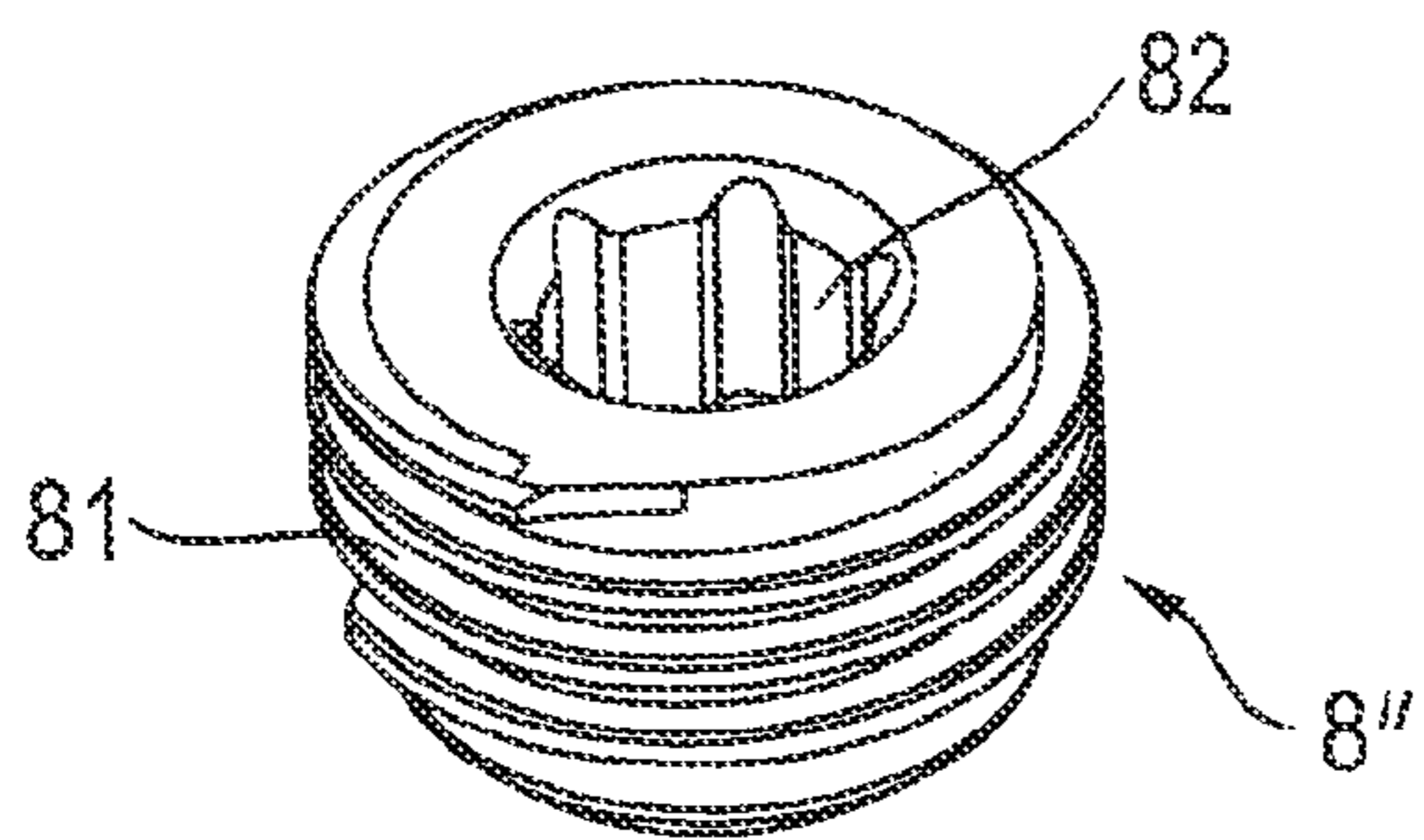
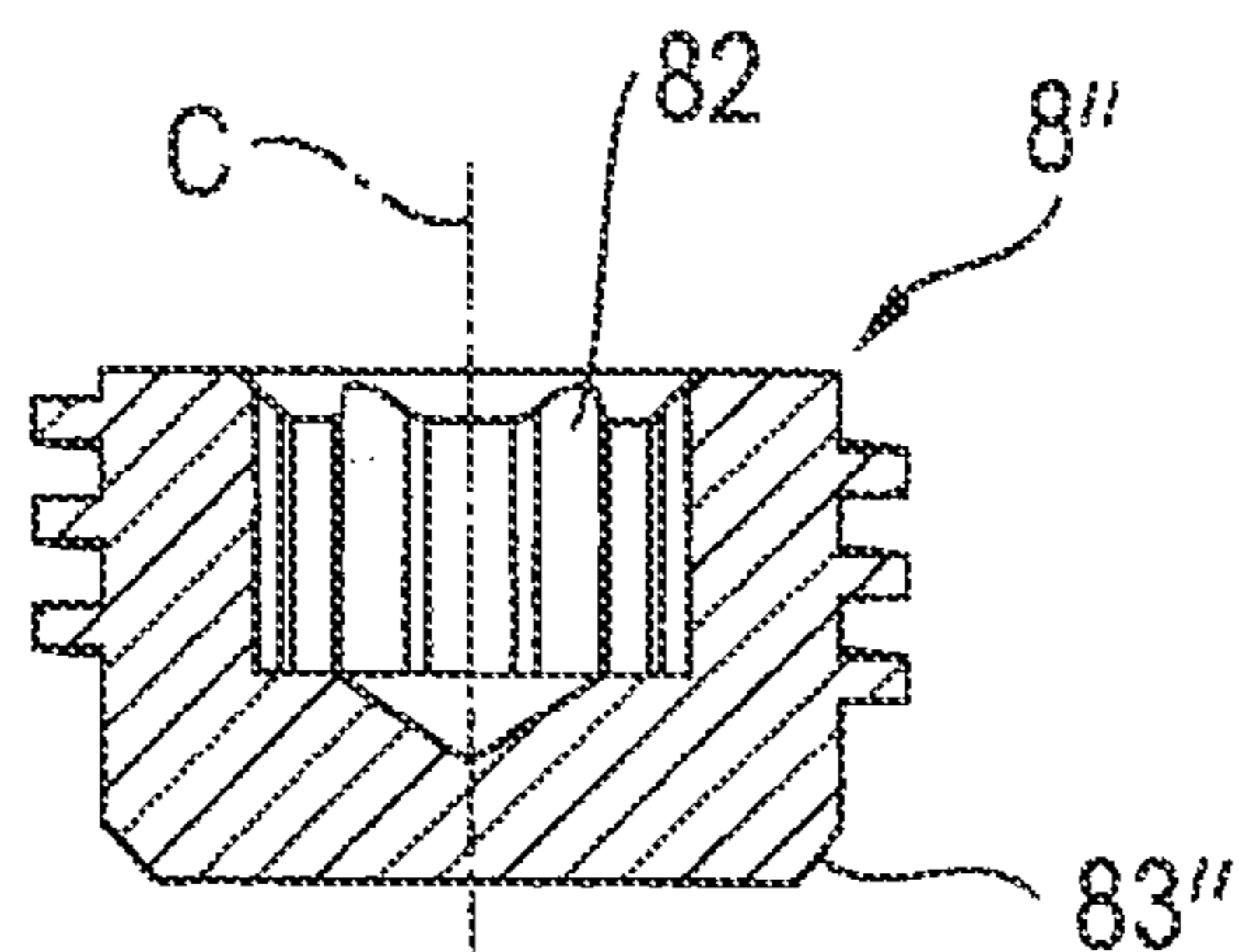


Fig. 14



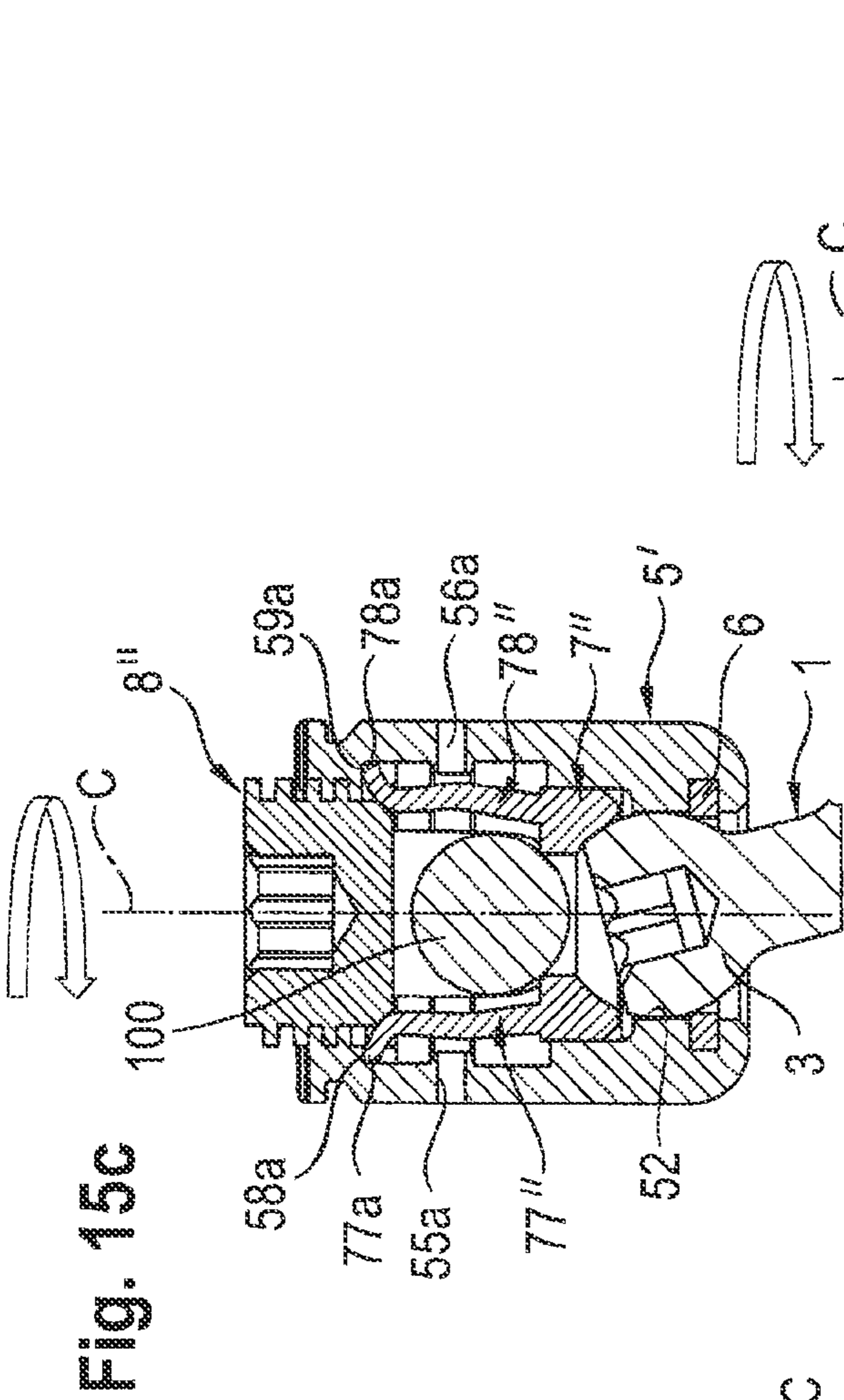


Fig. 15c

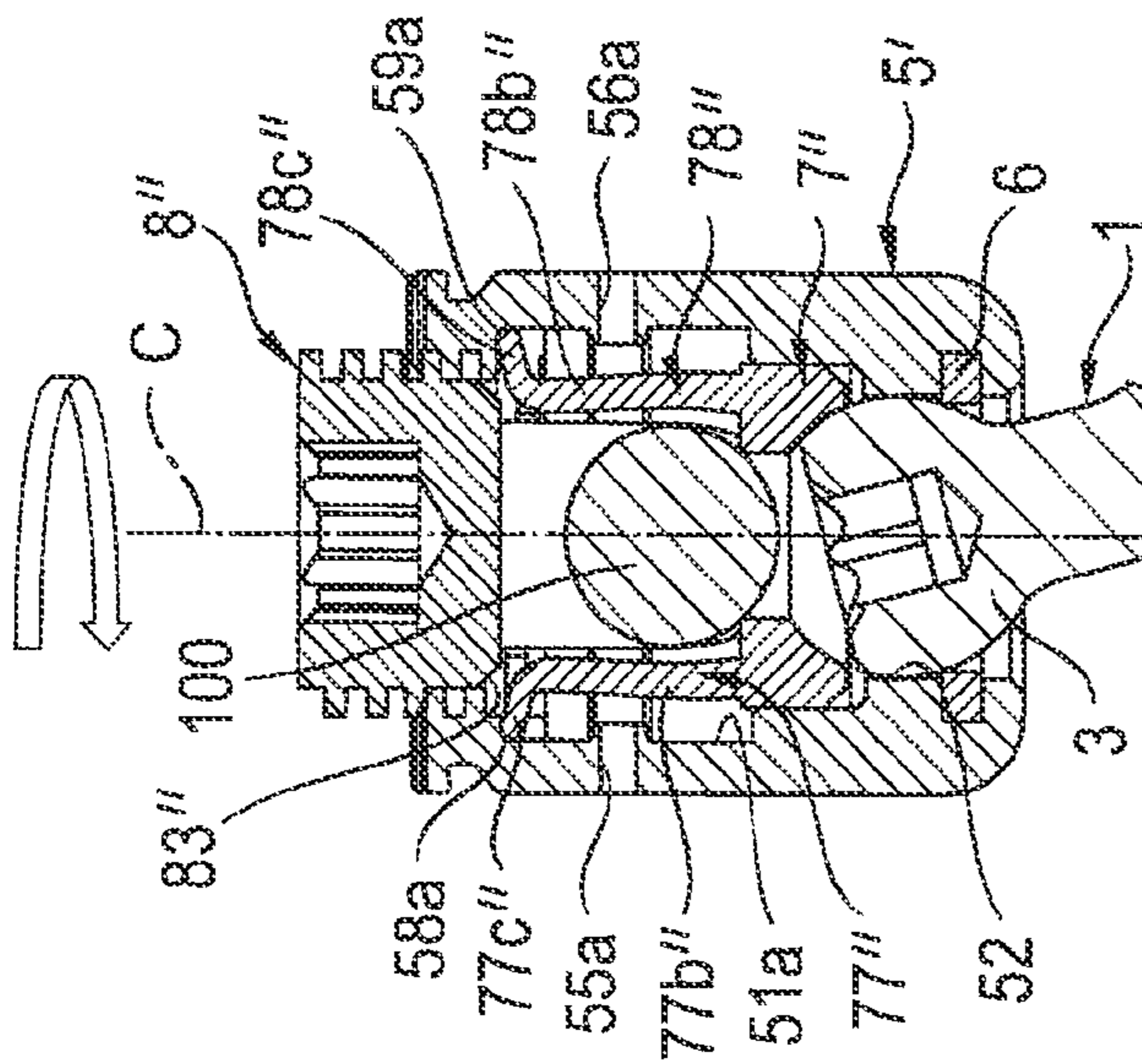


Fig. 15a

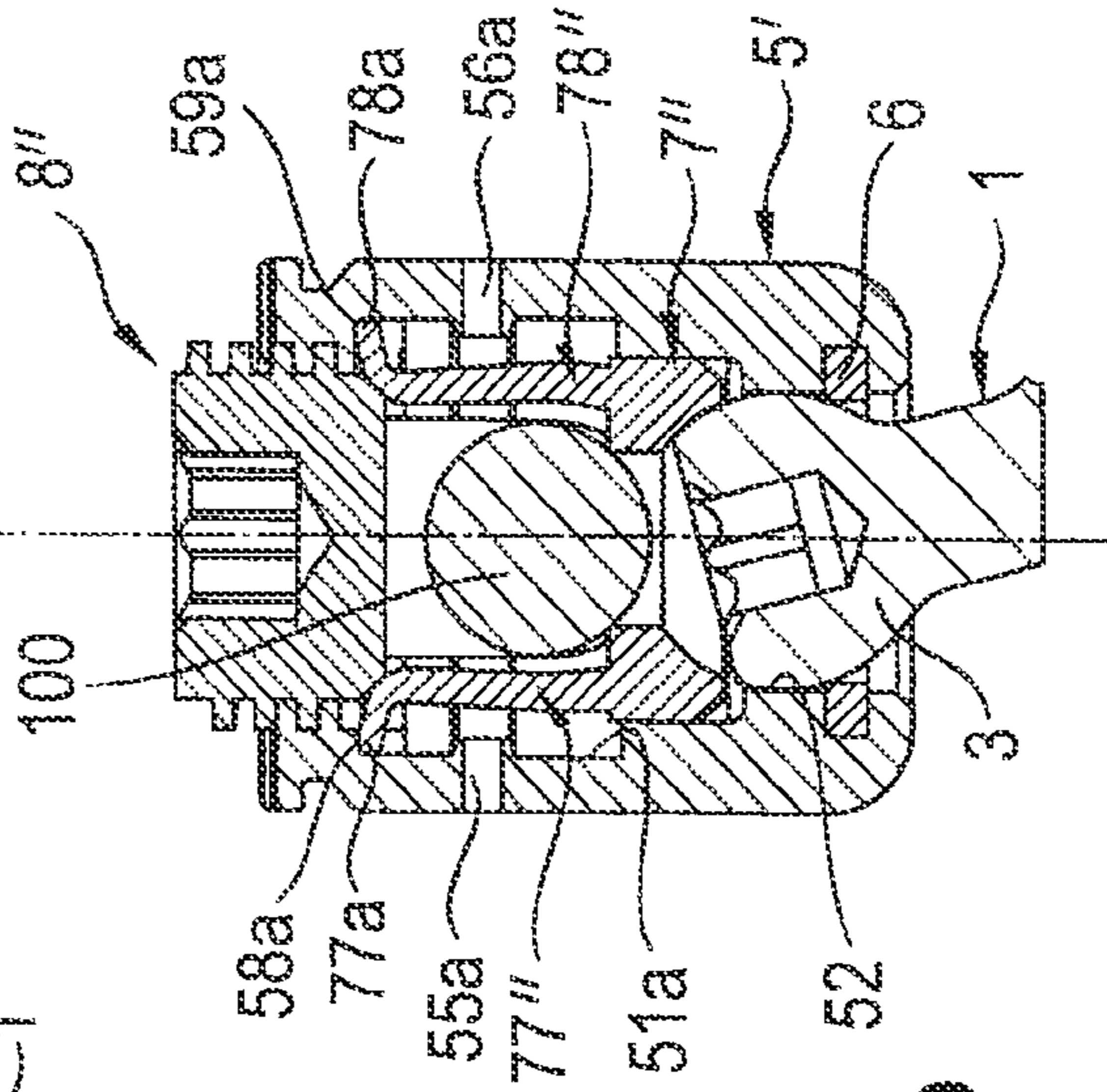


Fig. 15b

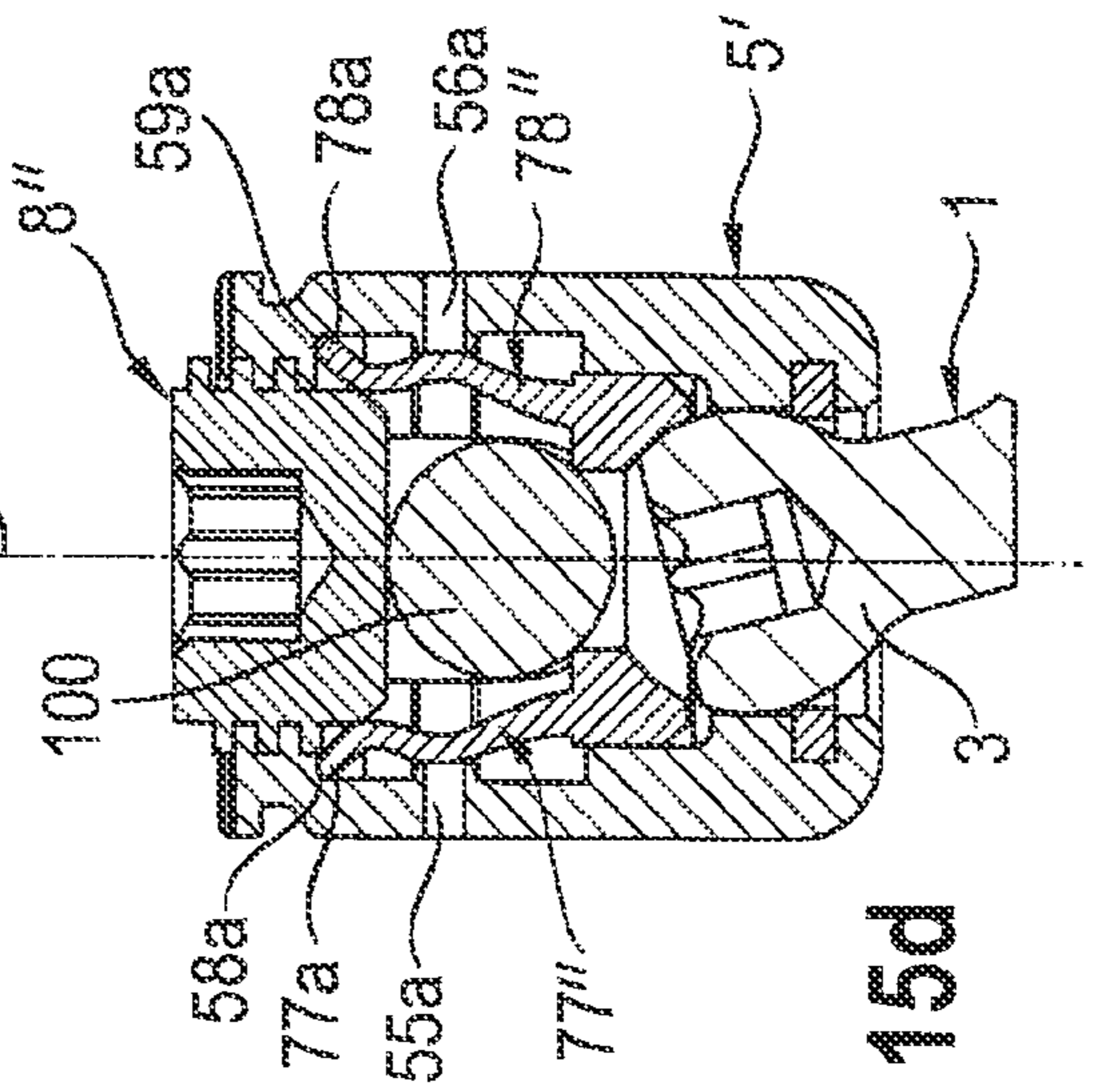


Fig. 15d

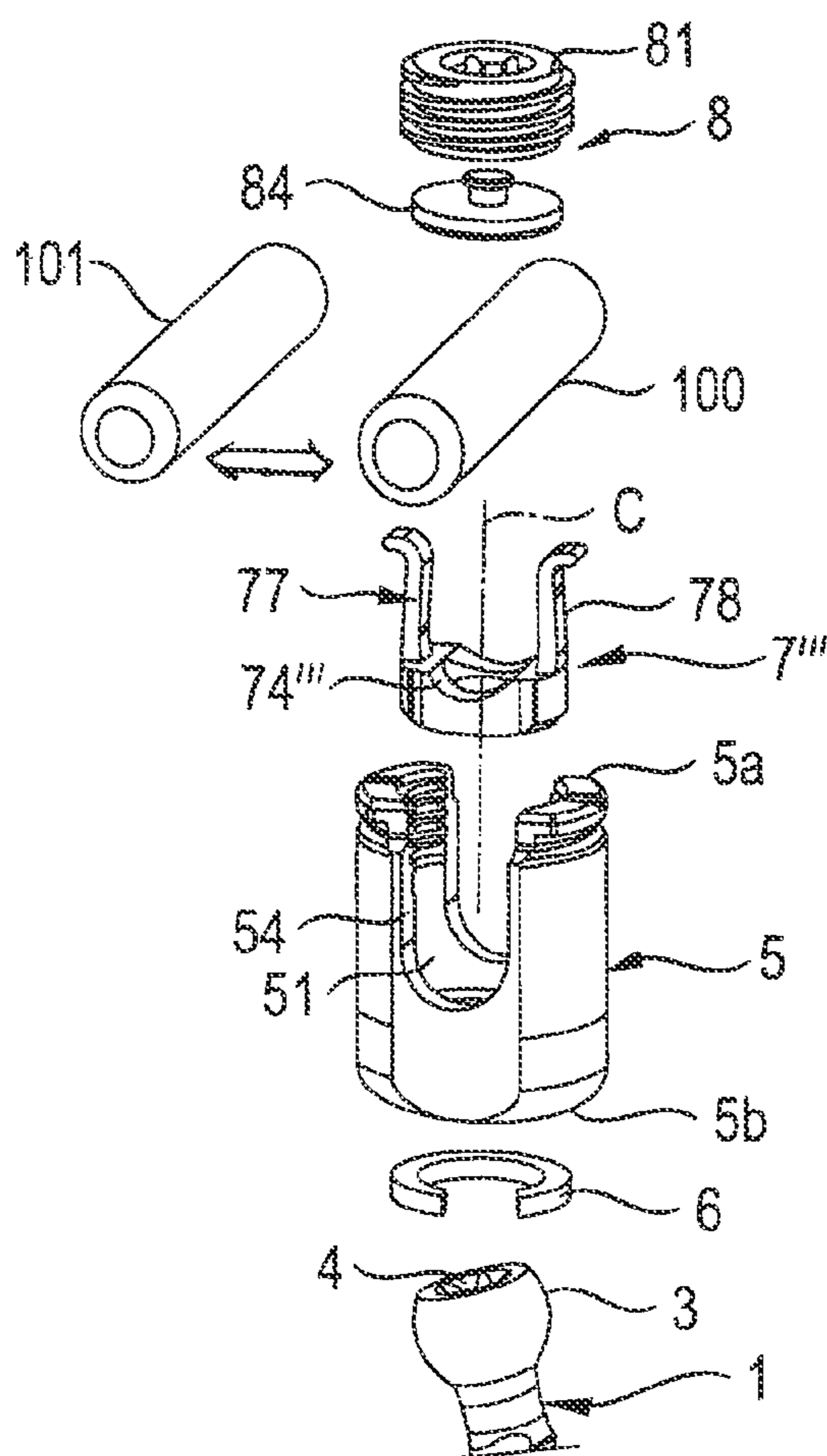


Fig. 16

Fig. 17a

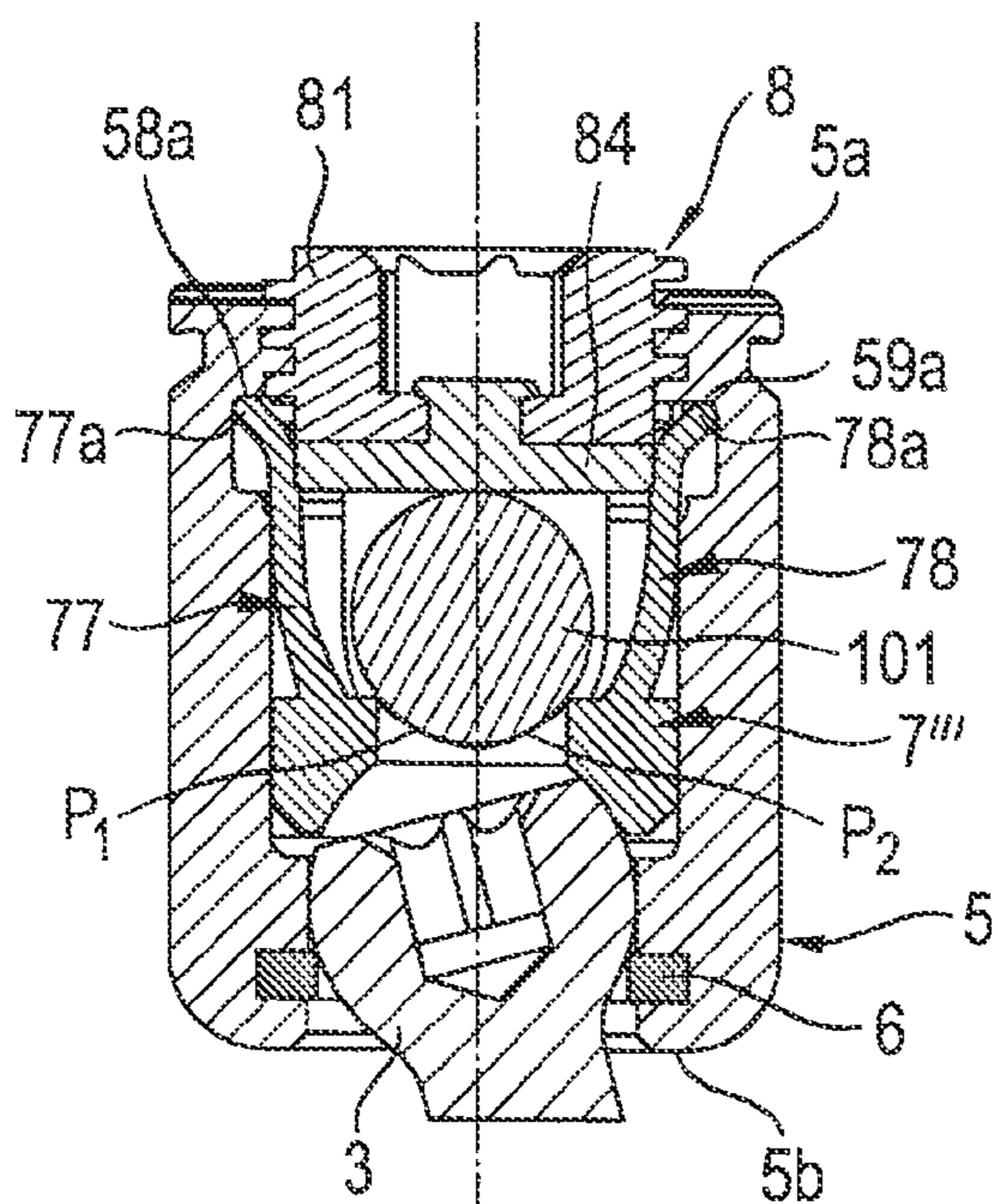
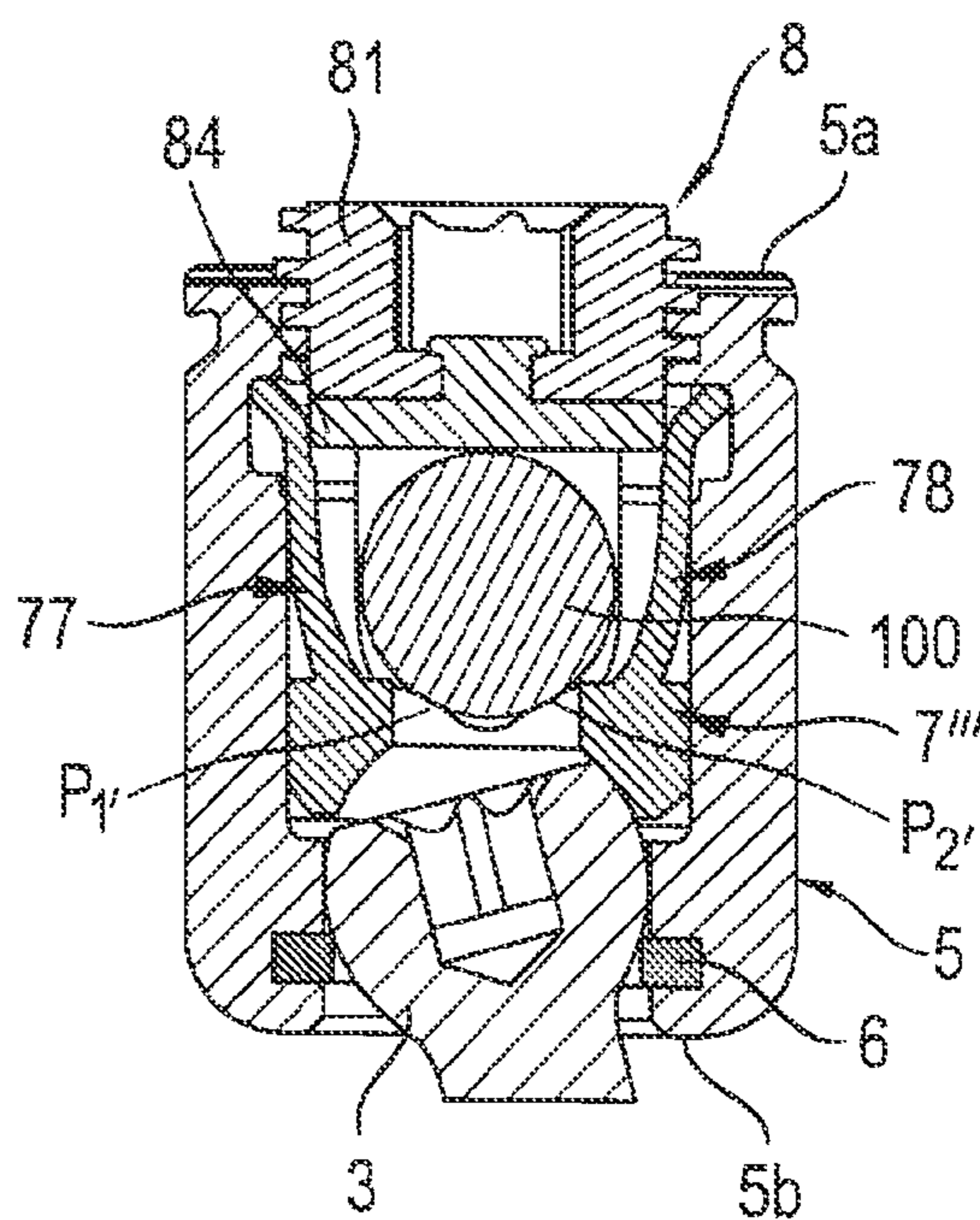


Fig. 17b



POLYAXIAL BONE ANCHORING DEVICE**CROSS-REFERENCE TO RELATED APPLICATIONS**

This application is a continuation of U.S. patent application Ser. No. 16/194,995, filed Nov. 19, 2018, which is a continuation of U.S. patent application Ser. No. 14/822,583, filed Aug. 10, 2015, now U.S. Pat. No. 10,159,519, which claims the benefit of U.S. Provisional Application Ser. No. 62/035,666, filed on Aug. 11, 2014, the contents of which are hereby incorporated by reference in their entirety, and claims priority from European Patent Application EP 14180588.7, filed on Aug. 11, 2014, the contents of which are hereby incorporated by reference in their entirety.

BACKGROUND

The invention relates to a polyaxial bone anchoring device, in particular for use in spinal or trauma surgery. The polyaxial bone anchoring device comprises a bone anchoring element with a shank to be anchored to a bone and a head. The head is pivotably held in a receiving part and can be locked at an angle relative to the receiving part by applying pressure onto it via a pressure member. With the receiving part, the bone anchoring element can be coupled to a stabilization rod that can be secured by a locking member. The pressure member comprises a deformable portion. First, the locking member applies a load to the pressure member that deforms the deformable portion whereby the head is locked. Thereafter the locking member comes into contact with the rod and locks the rod. The polyaxial bone anchoring device permits locking the head and the rod in a sequential manner, using a tool with a single drive portion that engages the locking member.

U.S. Pat. No. 8,088,152 B1 describes an orthopedic retaining system comprising at least one bone screw which has a head part and a shaft pivotably mounted thereon. A clamping sleeve is mounted in the head part, which can be pressed against the threaded shaft from its upper side to secure the threaded shaft relative to the head part. Further, a clamping device is provided by means of which the clamping sleeve and a retaining bar are pressed into the head part. The clamping device comprises an elastically deformable pressure member which is displaced into a clamping position during actuation of the clamping device.

US 2012/0253408 A1 describes a bushing for a bone screw assembly that includes a distal portion, a receiver portion, and a proximal portion. The distal portion includes a distal engagement surface that engages with a head of a bone screw. The receiver portion receives a fixation rod. The proximal portion includes a proximal engagement surface that engages with a locking member and a deformable portion that deforms from a first configuration to a second configuration based on a force applied by the locking member.

US 2013/0345761 A1 describes a polyaxial bone anchoring device comprising a bone anchoring element with a shank and a head and a receiving part pivotably coupled to the shank and having a channel for receiving a rod. A pressure member is arranged in a receiving part and is configured to exert pressure onto the head to lock the head in a receiving part. The pressure member has a deformable portion. Load applied to the pressure member by a locking member clamps the head and thereafter contacts the pressure

member such that the deformable portion is deformed and the locking member comes into contact with the rod and clamps the rod.

While known devices allow locking of the head of a bone anchoring device in the receiving part first and thereafter locking of the rod with a single instrument in a sequential manner, the necessary locking force for locking the devices is high. This results from the fact that the final step of clamping and locking the rod involves both the deformation of a deformable portion of the pressure member as well as a force applied for clamping and locking the rod. The force necessary for the deformation is lost for the clamping. Therefore, a relatively high force has to be applied to safely lock the rod.

SUMMARY

It is an object of the invention to provide a polyaxial bone anchoring device that allows for a sequential locking of the head and the rod to the receiving part with an instrument having a single drive portion and that requires a reduced force for locking. In addition, it is an object of the invention to provide a system of such a polyaxial bone anchoring device and at least two rods having different diameters where the bone anchoring device is configured to receive any of the rods and that provides a sequential locking function requiring a reduced force for locking.

The polyaxial bone anchoring device comprises a pressure member having a pressure exerting surface that exerts pressure onto the head and a deformable portion with a free end that is supported in the receiving part. In combination with a locking member, a force is exerted onto the deformable portion of the pressure member that deforms the deformable portion from a first configuration to a second configuration where the pressure exerted by the pressure member onto the head increases. Such a configuration allows for the deformable portion to function similar to a toggle lever that adjusts from an angled configuration when not clamped into a more substantially straight configuration when clamped. For locking the rod, the locking member is further advanced and tightened without a further deformation of the deformable portion of the pressure member. Therefore, a loss of force during locking of the rod due to deformation of the pressure member is reduced. This permits higher clamping forces acting onto the rod, and in turn, increases the safety of the locking.

In one embodiment, the deformable portion of the pressure member is elastically deformable and comprises a highly elastic material, in particular a material with super-elastic properties, such as a nickel-titanium (NiTi)-alloy, in particular Nitinol, or, for example, Beta-titanium. In this embodiment, due to the high elasticity of the deformable portion, a loss of force during deformation can be further reduced.

In one embodiment, the pressure member can be a monolithic piece made of such a highly elastic material. In another embodiment, only the deformable portion of the pressure member is made from the highly elastic material and is attached to another portion of the pressure member that may be manufactured from different material. This can reduce the manufacturing costs and facilitate easier manufacturing. Due to the elasticity of the deformable portion, size tolerances of the pressure member and the parts interacting therewith can be balanced.

In a still further embodiment, the locking of the head is maintained by the pressure exerted by the pressure member in the second configuration, even if the locking member is

3

loosened. Hence, further adjustments of the rod position are possible while the head still remains in the locked angular position relative to the receiving part. The deformable portion can be adjusted back to the first configuration, for example, by applying an instrument.

The polyaxial bone anchoring device according to the embodiments of the invention allows for a sequential locking, where first the head is locked and thereafter the rod is fixed by the application of a single instrument with a single drive portion. This facilitates easier handling of the polyaxial bone anchoring device during surgery.

In a still further embodiment, the pressure member is positioned in the receiver in the first configuration in such a manner that the pressure member exerts pressure onto the head to maintain the head by friction in a desired angular orientation before locking. This further facilitates adjustment of the orientation of the receiving part relative to the bone anchoring element before inserting the rod.

The polyaxial bone anchoring device may be of a top loading type, where the bone anchoring element is inserted into the receiving part from a top side, i.e. the side from which the locking member is inserted. Alternatively, the bone anchoring device may be of a bottom loading type, where the head of the bone anchoring element is inserted into the receiving part from a bottom side, i.e. from the side opposite to where the locking member is inserted.

In a still further embodiment, a support surface of the pressure member for supporting the rod is configured to support rods having different diameters. This allows use of the sequential locking mechanism with different rods using one single polyaxial bone anchoring device, regardless of the size of the rod.

BRIEF DESCRIPTION OF THE DRAWINGS

Further features and advantages of the invention will become apparent from the description of embodiments by means of the accompanying drawings. In the drawings:

FIG. 1 shows a perspective exploded view of a polyaxial bone anchoring device according to a first embodiment.

FIG. 2 shows a perspective view of the polyaxial bone anchoring device according to the first embodiment in an assembled state.

FIG. 3 shows a perspective view from a top of a receiving part of the polyaxial bone anchoring device according to the first embodiment.

FIG. 4 shows a perspective view from a bottom of the receiving part of the polyaxial bone anchoring device according to the first embodiment.

FIG. 5 shows a top view of the receiving part of FIGS. 3 and 4.

FIG. 6 shows a cross-sectional view of the receiving part of FIGS. 3 to 5, the cross-section taken along line A-A in FIG. 5.

FIG. 7 shows a perspective view of a pressure member of the polyaxial bone anchoring device according to the first embodiment.

FIG. 8 shows a perspective exploded view of a locking member of the polyaxial bone anchoring device according to the first embodiment.

FIG. 9 shows a cross-sectional view of the locking member of FIG. 8, the cross-section taken in a plane containing a central axis of rotation of the locking member.

FIGS. 10a to 10f show respective cross-sectional views of the polyaxial bone anchoring device according to the first embodiment that illustrate the steps of inserting and advanc-

4

ing the locking member into the receiving part for locking the head and the rod in a sequential manner.

FIG. 11 shows a perspective exploded view of a modified pressure member of the polyaxial bone anchoring device according to the first embodiment.

FIG. 12 shows a perspective exploded view of a further modification of a two-part locking member.

FIG. 13 shows a perspective view of a modified locking member of the polyaxial bone anchoring device according to the first embodiment.

FIG. 14 shows a cross-sectional view of the locking member of FIG. 13.

FIGS. 15a to 15d show cross-sectional views, respectively, of a polyaxial bone anchoring device according to a second embodiment, illustrating steps of inserting and advancing the locking member to lock the head and the rod in a sequential manner.

FIG. 16 shows a perspective exploded view of a system including a polyaxial bone anchoring device and two rods having different diameters.

FIG. 17a and FIG. 17b show cross-sectional views of the polyaxial bone anchoring device of FIG. 16, with the inserted rods having different diameters, respectively.

DETAILED DESCRIPTION

A polyaxial bone anchoring device according to a first embodiment is shown in FIGS. 1 and 2. The polyaxial bone anchoring device comprises an anchoring element 1 having a shank 2 with a threaded portion and a head 3. The head 3 has a spherically-shaped outer surface portion and, on its side opposite to the shank 2, a recess 4 for engagement with a tool. A receiving part 5 is provided for coupling the bone anchoring element 1 to a rod 100. The polyaxial bone anchoring device in FIGS. 1 and 2 is of the bottom loading type, i.e. the bone anchoring element 1 is inserted into the receiving part 5 from a bottom end of the receiving part 5. To retain the head 3 in the receiving part, a retainer element 6 is provided. In addition, a pressure member 7 is arranged in the receiving part to exert pressure onto the head 3 of the bone anchoring element 1. For locking the head 3 and the rod 100 relative to the receiving part 5, a locking member 8 is provided that is insertable into the receiving part 5.

Referring further to FIGS. 1 to 6, the receiving part 5 has a first end or top end 5a, a second end or bottom end 5b, and has a substantially cylindrical construction, with a longitudinal axis C that goes through the top end 5a and the bottom end 5b. Coaxial with the longitudinal axis C, a first coaxial bore 51 is provided extending from the top end 5a to a predetermined distance from the bottom end 5b. A second coaxial bore 52 with a smaller diameter than that of the first bore 51 extends from the bottom end 5b into the first bore 51 and serves as an accommodation space for the head 3. The second bore 52 leads into a bottom opening 52a with an inner diameter greater than the outer diameter of the head 3 at the bottom end 5b. This permits insertion of the head 3 through the opening 52a from the bottom end 5b. Furthermore, at a distance from the second end 5b, an annular groove 53 is provided for accommodating the retainer element 6. An axial length of the second bore 52 is such that when the head 3 is retained by the retainer element 6, an uppermost portion of the head 3 protrudes into the first bore 51 and is configured to be engaged by the pressure member 7. It shall be noted that the diameter of the first bore 51 does not need to be larger than the diameter of the second bore 52.

The receiving part 5 further comprises a U-shaped recess 54 starting at the top end 5a and extending in the direction

of the bottom end **5b**. By means of the U-shaped recess **54**, two free legs **55**, **56** are formed that define a channel for receiving the rod **100**. Adjacent to the top end **5a**, an internal thread **57** is provided at the inner surface of the legs **55**, **56**. In the embodiment shown, the internal thread **57** is a flat thread having substantially horizontal upper and lower thread flanks. Any other thread form can be used for the internal thread **57**. A thread form that reduces or eliminates splaying of the legs **55**, **56**, however, is preferable.

As depicted in particular in FIGS. **3** and **6**, two recesses **58**, **59** are formed at an inner wall of the legs **55**, **56**, respectively, that have the purpose of accommodating a portion of the pressure member **7** therein. The recesses **58**, **59** are located at substantially the center of each leg **55**, **56** in the circumferential direction and at a lower portion of the thread **57** in the axial direction. An upper wall **58a**, **59a** or an upper corner of the recesses **58**, **59** forms a support for the pressure member **7** as explained below.

As can be seen in FIGS. **1**, **7** and **10a** to **10f**, the pressure member **7** has a substantially cylinder-segment shaped central portion **71** and two side flanges **72**, **73** provided on opposite sides of the central portion **71** and also having cylindrical outer surface portions. At a top surface **7a** of the pressure member **7** between the flanges **72**, **73**, a rod supporting surface **74** is provided in the form of a substantially cylinder segment-shaped recess with a cylinder axis being perpendicular to a central axis **C** that is configured to coincide with the central axis **C** of the receiving part **5**. The radius of the cylinder segment-shaped rod supporting surface **74** can match the radius of a rod **100** to be supported thereon. The pressure member **7** further comprises a substantially spherical recess **75** opposite to the upper surface **7a** with a radius of the sphere matching the radius of the spherical head **3**. The inner surface of the recess **75** forms a pressure-exerting surface. A lower edge of the recess **75** forms a bottom end **7b** of the pressure member **7**. In addition, a coaxial through-hole **76** extends through the central portion **71** to allow access with a driver or another instrument to the head **3**.

As shown in FIG. **7**, two upstanding arms **77**, **78** protrude from the upper surface **7a** of the pressure member **7**. The arms **77**, **78** are respectively positioned substantially at the middle of the upper surface **7a** of the flanges **72**, **73** and each arm **77**, **78** has a substantially rectangular cross-section. In the embodiment shown, a long side of the rectangle is substantially parallel to the cylinder axis of the rod supporting surface **74** and is smaller than a width of the flanges **72**, **73** in this same direction. A width of each of the arms **77**, **78** in a direction perpendicular to the cylinder axis of the rod supporting surface **74** is also smaller than the width of the flanges **72**, **73** in this same direction, so that the arms **77**, **78** are spaced apart from the edges of the flanges **72**, **73**. In addition, the thickness of the arms **77**, **78** decreases in an upward direction.

As further shown in FIG. **7**, each arm **77**, **78** comprises a free end **77a**, **78a**. Adjacent to the upper surface **7a** of the pressure member **7**, each of the arms **77**, **78** has a substantially vertically extending long portion **77b**, **78b**. From the end of the long portions **77b**, **78b**, short portions **77c**, **78c** extend radially outward and away from the long portions **77b**, **78b** at an angle α of substantially 90° or greater. The long portions **77b**, **78b** may be twice as long as the short portions **77c**, **78c** or longer. The length of the arms is such that the long portions **77b**, **78b** extend above an upper surface of a rod that is placed onto the rod support surface **74**.

In this embodiment, the pressure member **7** is a monolithic piece. It may be formed entirely from a highly elastic material. Such a material can be, for example, a metal or a metal alloy having superelastic properties. Such metal alloy can be, for example, a nickel-titanium alloy (NiTi alloy), such as Nitinol, or Beta-titanium. However, other materials that can provide the necessary high elasticity can also be used.

Due to the shape and the material, the arms **77**, **78** are flexible. In particular, in a first configuration, the arms **77**, **78** are in their resting position that is defined by the bent shape as shown in FIG. **7**, wherein the short portions **77c**, **78c** form an obtuse angle α with the long portions **77b**, **78b**. In a second configuration, the arms **77**, **78** are deformed such that the angle α between the short portions **77c**, **78c** and the long portions **77b**, **78b** is increased, and the long portions may be deflected outward. In the second configuration, a load can be transferred through the arms **77**, **78** onto the head **3**. In other words, the pressure member **7** can behave similar to toggle levers formed by the arms **77**, **78**, that act between the receiving part **5** and the head **3**, where a bending area of the arms **77**, **78** corresponds to a middle point of rotation or, for example, a pivot point of a toggle level.

As can be seen in particular in FIGS. **10a** to **10f**, when the pressure member **7** is inserted into the receiving part **5** and the free ends **77a**, **78a** of the arms **77**, **78** abut against the support surfaces **58a**, **59a** in the recesses **58**, **59**, the pressure member is accommodated in the first bore **51** such that a gap exists between the lower edge **7b** of the pressure member **7** and the bottom of the first bore **51**.

As depicted in FIG. **1** and FIGS. **10a** to **10f**, the retaining element **6** is formed as a slotted ring having a slot **61** that renders the retainer element **6** radially compressible and expandable. The outer size of the retainer element **6** is such that the retainer element **6** can be inserted into the groove **53** in a slightly compressed manner, and is held in the groove **53** under a pre-load.

Referring now in particular to FIGS. **1** and **2** as well as FIGS. **8** to **10f**, the locking member **8** is a two-part locking member that includes a set screw **81** and a washer **84** rotatably connected to the set screw **81**. The set screw **81** is configured to engage the internal thread **57** of the legs **55**, **56** and has an engagement portion **82** for a driver on its upper side. A through-hole **83** may be provided on the lower side of the set screw **81**. The washer **84** may be connected to the set screw **81** with a central coaxial pin **85** that extends through the through-hole **83** and is deformed on the other side of the through hole **83** to provide a rivet-like connection. A lower edge **84a** of the washer **84** is rounded. This ensures a smooth sliding contact between the locking member **8** and the pressure member **7**. The washer **84** may have a same outer contour as a portion of the set screw **81**.

The receiving part **5**, the retainer element **6**, the bone anchoring element **1** and the locking member **8** can each be made of a material that is different from the material of the pressure member **7**. In particular, the materials used can be any body-compatible material such as a body-compatible metal or metal alloy, such as stainless steel, titanium or a body-compatible plastic, such as polyetheretherketone (PEEK). The parts can all be made of the same or of different materials. In a still further embodiment, all parts of the polyaxial bone anchoring device can be made of the same material as the pressure member **7**.

The bone anchoring device may be preassembled as follows. In a first method of assembly, the head **3** of the bone anchoring element **1** is inserted in the receiving part **5** through the lower opening **52a**. Then, the retaining element

7

6 is compressed and inserted into the groove 53 from the lower opening 52a. Once the retaining element 6 is in the groove 53, the head 3 is pivotably held by the retaining element 6 and cannot be removed through the lower opening 52a. In an alternative method of assembly, the retaining element 6 is placed into the groove 53 and the bone anchoring element 1 is then inserted through the top end 5a of the receiving part 5, such that the shank 2 extends through the lower opening 52a and the head 3 rests on the retaining element 6. The retaining element 6 prevents the head 3 from being pulled through the lower opening 52a of the receiving part 5.

The pressure member 7 is inserted through the top end 5a in an orientation in which the cylinder axis of the rod supporting surface 74 is aligned with the longitudinal axis of the U-shaped recess 54 of the receiving part. The arms 77, 78 of the pressure member 7 are slightly compressed towards each other during insertion, such that the free ends 77a, 78a of the arms 77, 78 snap into the recesses 58, 59 of the receiving part 5 and are supported by the upper wall 58a, 59a of the recesses 58, 59, respectively, as depicted in FIGS. 10a to 10f. The pressure exerting surface 75 of the pressure member 7 at least partially contacts the outer surface of the head 3. The dimensions of the pressure member 7 may be such that, in the assembled state when the head 3 is not yet locked relative to the receiving part 5, the pressure member 7 exerts a pre-stress onto the head 3 that maintains the bone anchoring element 1 in the receiving part 5 at a desired angular orientation relative to the receiving part 5 before locking by means of friction between the pressure exerting surface 75 and the head 3.

As illustrated in FIGS. 10a to 10c, at least a central portion of the arms 77, 78 is spaced apart from the inner wall of the first bore 51, such that there is a gap between the inner wall of the first bore 51 and an outer surface of the arms 77, 78 that allows the arms 77, 78 to be deflected outward.

The use and function of the polyaxial bone anchoring device will be explained referring to FIGS. 10a to 10f. Usually, at least two bone anchoring elements 1 are inserted into bone parts or adjacent vertebrae and the U-shaped recesses 54 of the corresponding receiving parts 5 are aligned to receive the rod 100. As depicted in FIG. 10a, the locking member 8 is screwed in between the legs 55, 56. When the locking member 8 is further screwed in, the lower rounded edge 84a of the washer 84 contacts the short portions 77c, 78c of the arms 77, 78 near the transition to the long portions 77b, 78b (FIG. 10b). Because the washer 84 is rotatably connected to the set screw 81, the washer 84 basically does not rotate when the set screw 81 is further advanced into the receiving part 5. This results in the forces exerted by the locking member 8 onto the arms 77, 78 being substantially axial, where radial forces and transverse forces are reduced.

The locking member 8 exerts a force onto the arms 77, 78 that deforms the arms 77, 78 as can be seen in FIGS. 10c and 10d. Thereby, the arms 77, 78 of the pressure member 7 tend to become more straightened as the locking member 8 is advanced in the receiving part 5. Because the free ends 77a, 78a of the arms 77, 78 are supported in the receiving part 5 and the pressure exerting surface 75 is supported on the head 3, which itself is supported on the retaining element 6, there is limited or no space for the arms 77, 78 to extend in the axial direction, so the long portions 77b, 78b of the arms 77, 78 are deflected radially outward as depicted in FIGS. 10c to 10e. The deformation of the arms 77, 78 results in a continuously increasing pressure on the head 3.

8

As illustrated in FIG. 10f, the long portions 77b, 78b of the arms 77, 78 are further deformed outward during tightening of the locking member 8 and extend into the space provided by the first bore 51. When the arms 77, 78 are in the second configuration as shown in FIG. 10e, the head 3 is fully locked by the pressure exerted onto it by the pressure member 7. The second configuration is maintained even if the locking element 8 is advanced further downward and thereby slides along the inner side of the arms 77, 78, so that the advancement of the locking element 8 may require only little force. In the second configuration prior to locking the rod 100, the rod 100 is still movable because the locking member 8 is not in contact with the rod 100.

Finally, as depicted in FIG. 10f, further tightening of the locking member 8 advances the locking member 8 towards the rod surface, until the rod 100 is fixed by the pressure exerted onto it by the locking member 8.

In the first embodiment, a loosening of the locking member 8 causes the arms 77, 78 to return to the first configuration due to the high elasticity of the arms 77, 78. After loosening the locking member 8, the positions of the head 3 and the rod 100 relative to the receiving part 5 can be adjusted again.

FIG. 11 shows a modification of the pressure member. All portions that are identical or similar to the portions of the pressure member 7 of the first embodiment are marked with the same reference numerals, and the descriptions thereof will not be repeated. The pressure member 7' has arms 77', 78' that are separate pieces from the main part 71 and that are insertable into recesses 72a, 73a in the upper surface 7a of the flanges 72, 73. The separate arms 77', 78' are connected to the pressure member 7, for example, by a press-fit connection or any other connection that prevents inadvertent disassembly. In the pressure member 7', only the arms 77', 78' are made from a highly elastic material, such as a material exhibiting superelastic properties like a nickel-titanium (NiTi) alloy, for example Nitinol or, for example, Beta-titanium. The main part 71 and the flanges 72, 73 can be made from another material, such as stainless steel or titanium or any other body compatible material. With this embodiment, the manufacturing of the pressure member 7' can be more easily facilitated and costs can be saved.

FIG. 12 shows a perspective exploded view of a modified locking member. The locking member 8' is a two-part locking member that comprises the set screw 81 and a washer 84' that can be rotatably connected to the set screw 81, for example, by a rivet-like connection. The washer 84' has a substantially rectangular main portion 86 and two opposite cylinder-segment shaped flanges 87, 88 that extend from the main portion 86 on opposite sides. The flanges 87, 88 each have substantially vertically extending and substantially flat outermost surface portions 87a, 88a, with a width that is substantially the same or greater than the widths of the arms 77, 78 of the pressure member 7. Such a configuration allows for the washer 84' to more smoothly slide along the inner surface of the arms 77, 78 of the pressure member 7 that faces towards the central axis C when the locking member 8' is advanced in the receiving part 5. The substantially flat vertical surface portions 87a, 88a allow for a better transfer of the pressure force applied by the washer 84' onto the arms 77, 78. The rectangular main portion 86, for example, extends into the U-shaped recess 54 of the receiving part 5 and prevents the washer 84' from rotating when the set screw 81 is screwed in. Therefore, the occurrence of transverse forces acting onto the arms 77, 78 can be decreased or avoided.

In a further modification depicted in FIGS. 13 and 14, the locking member 8" is monolithic. The locking member 8" is formed as a set screw with an engagement portion 82 and a beveled lower edge 83" opposite to the engagement portion 82. The beveled lower edge 83" ensures that sufficient pressure is exerted onto the arms 77, 78 when the locking member 8" is moved downward in the bore 51.

A second embodiment of the polyaxial bone anchoring device will be described with reference to FIGS. 15a to 15d. The second embodiment of the polyaxial bone anchoring device differs from the first embodiment in the design of the receiving part and the pressure member. The locking member used in this embodiment is the single part locking member 8" as described before. However, the two-part locking members as described before can also be used.

The receiving part 5' comprises an enlarged bore section 51a that is provided approximately in the middle of the receiving part 5' in an axial direction. The enlarged bore section 51a serves to provide more space for deforming the arms 77", 78" of the pressure member 7". In addition, two transverse through bores 55a, 56a are respectively positioned in a transverse direction at substantially the centers of the legs 55, 56. The through bores 55a, 56a are configured to permit access to the first bore 51 with an instrument.

As depicted in particular in FIG. 15a, the pressure member 7" differs from the previously discussed pressure members with respect of the shape of the arms 77", 78". The arms 77", 78" have long portions 77b", 78b" that are slightly bent outward near the upper surface 7a of the main body of the pressure member 7". Furthermore, the short portions 77c", 78c" each form an angle of 90° or only slightly larger than 90° with the respective long portions 77b", 78b". The bending properties of the arms 77", 78" are different from the arms 77, 78 of the first embodiment. When pressure is exerted onto the short portions 77c", 78c" near the bending area (i.e., the area between the short portions 77c", 78c" and the long portions 77b", 78b"), the pressure exerted onto the arms 77c", 78c" deforms the vertical long portions 77b", 78b" outward so that the arms 77", 78" assume an approximate S-shape (FIG. 15d).

As illustrated in FIGS. 15a and 15b, the locking member 8" can be screwed into the receiving part 5' until the beveled edge 83" abuts against the arms 77", 78" in the region of the bending area (FIG. 15b). Further advancement of the locking member 8" results in an outward bending of the long portion 77b", 78b" of the arms 77", 78" (FIG. 15c). In this configuration, the pressure exerted onto the head 3 is increased. Further screwing in of the locking member 8" results in a deformation of the arms 77", 78" to an approximate S-shape, whereby the long portions 77b", 78b" snap outward, for example, like a flip-flop. In this configuration, the head 3 is locked. The locking member 8" can be further advanced until it presses onto the upper surface of the rod 100, resulting in a locking of the rod 100 (FIG. 15d).

In the configuration shown in FIG. 15d, the deformation of the arms 77", 78" remains permanent, unless the arms 77", 78" are deformed back to their original shapes. Hence, the locking member 8" can be unscrewed in order to readjust the position of the rod 100 relative to the receiving part 5', while the angular position of the head 3 relative to the receiving part 5' remains locked. In this embodiment, the locked head 3 can be unlocked by applying an instrument that extends through the through bores 55a, 56a and pushes the arms 77", 78" back into their original positions.

Referring to FIG. 16, a third embodiment of the polyaxial bone anchoring device is shown. Parts and portions that are identical or similar to the previous embodiments have the

same reference numerals, and the descriptions thereof will be not repeated. In this embodiment, the pressure member 7"" comprises a rod supporting surface 74"" that has a substantially v-shaped cross-section in a plane perpendicular to a longitudinal axis of the rod supporting surface 74"". As shown in FIG. 16, such a configuration facilitates using rods 100, 101 that have different diameters with the polyaxial bone anchoring device. As depicted in FIG. 17a, a rod 101 with a smaller diameter compared to the rod 100 is supported on the rod supporting surface 74"" of the pressure member 7"". The rod 101 is supported along opposite lines of contact P1, P2 that extend along the length of the rod supporting surface 74"". The arms 77, 78 of the pressure member 7"" extend above the surface of the inserted rod 101. As in the previous embodiments, the locking member 8 can be screwed in to first lock the head 3 relative to the receiving part 5' and thereafter lock the rod 101 relative to the receiving part 5'. As shown in FIG. 17b, the rod 100 with a diameter greater than that of the rod 101 can be supported at substantially two contact lines P1', P2' that may be positioned higher from the bottom of the rod supporting surface 74"" than the position of the contact lines P1, P2 when the rod 101 is used. When the rod 100 is used, the arms 77, 78 can also extend above the surface of the rod 100. Advancing the locking member 8 into the receiving part 5 first locks the head 3 relative to the receiving part 5 and thereafter locks the rod 100 relative to the receiving part 5.

In this embodiment, a system including the polyaxial bone anchoring device and at least two rods having different diameters where the bone anchoring device is configured to receive any of the rods can be provided. This allows the surgeon to select an appropriate rod depending on the desired application.

Further modifications of the above described embodiments are also possible. For example, the parts and portions of the different embodiments can be mixed and matched. It also is possible to use any of the described locking members for any of the embodiments of the polyaxial bone anchoring devices described herein. The various pressure members and locking members described before can also be selected and combined.

For the receiving part, other designs are possible, such as a typical top loading design where the bone anchoring element can only be inserted from the top end of the receiving part, or any other bottom loading design where the bone anchoring element can be inserted from the bottom end of the receiving part, as long as the free end of the deformable portions of the pressure member can be supported in the receiving part and the receiving part provides space for the deformation of the deformable portions. The receiving part may be designed such that enlarged pivot angles in a particular direction are possible.

The arms of the pressure member can also have many different shapes as long as a deformation from a first condition to a second configuration is possible. Even one single arm may be sufficient in some embodiments. The arms need not be continuous pieces. For example, it is possible to construct the arms from two substantially rigid levers that are connected via a hinge to form a toggle lever. In this case, the deformation may involve, for example, bringing the toggle lever from a first, angled configuration to a second, more substantially straight configuration.

For the bone anchoring element, different kinds of bone anchoring elements can be used, such as screws, nails, cannulated anchors, hooks, etc. The head and the shank may be constructed from two pieces that connect together. Although the head in the described embodiments is shown

11

to have a spherical segment shape in such a manner that the bone anchoring element is polyaxially pivotable with respect to the receiving part, in some embodiments, the head and/or the receiving part or the pressure member may instead be designed such that pivoting can only take place, for example, in one single plane.

The pressure exerting surface of the pressure member may be in direct contact with the head, or may instead be operatively in contact with the head via, for example, an intermediate part.

In some embodiments, the function of the locking member can also be realized by an instrument. Other kinds of locking members can also be used that are configured to apply similar loads to the pressure member.

While the present invention has been described in connection with certain exemplary embodiments, it is to be understood that the invention is not limited to the disclosed embodiments, but is instead intended to cover various modifications and equivalent arrangements included within the spirit and scope of the appended claims, and equivalents thereof.

The invention claimed is:

1. A polyaxial bone anchoring device comprising:

a bone anchoring element comprising a shank for anchoring to a bone and a head;

a receiving part comprising a first end, a second end, a longitudinal axis extending through the first end and the second end, a channel at the first end for receiving a rod, and an accommodation space for pivotably holding the head;

a pressure member configured to be positioned in the receiving part and to exert pressure onto the head to lock the head in the receiving part, the pressure member comprising a pressure exerting surface and a deformable portion comprising a free end, wherein the deformable portion is configured to assume at least a first configuration and a second configuration; and

a locking member configured to be inserted into the channel to move in the channel along the longitudinal axis and to exert a force onto the deformable portion of the pressure member;

wherein when the head is in the receiving part, and when the deformable portion of the pressure member is in the first configuration and the locking member is in contact with the deformable portion at a first axial position relative to the receiving part, the free end of the deformable portion is supported by the receiving part and the locking member is moveable towards the head to exert a force on the deformable portion for adjusting the deformable portion from the first configuration to the second configuration, and wherein when the head is in the receiving part, and when the deformable portion of the pressure member is in the second configuration and the locking member is in contact with the deformable portion at a second axial position relative to the receiving part, the pressure member exerts a force on the head that locks the head relative to the receiving part, and the locking member is further moveable towards the head.

2. The polyaxial bone anchoring device of claim 1, wherein the deformable portion is elastically deformable.

3. The polyaxial bone anchoring device of claim 1, wherein the deformable portion comprises a nickel-titanium alloy.

4. The polyaxial bone anchoring device of claim 1, wherein when the head and pressure member are in the receiving part, the pressure exerting surface of the pressure

12

member faces the head and the deformable portion is on the side of the pressure member opposite to the pressure exerting surface.

5. The polyaxial bone anchoring device of claim 1, wherein in the first configuration, the deformable portion is configured to protrude radially into a path of the locking member when the locking member is advanced into the channel.

6. The polyaxial bone anchoring device of claim 1, wherein the deformable portion of the pressure member comprises one or more legs extending on a rod support surface.

7. The polyaxial bone anchoring device of claim 6, wherein the deformable portion comprises a free end, wherein at least one of the legs comprises a long portion and a short portion, the free end being provided at the end of the short portion, and wherein the long portion extends up to a height greater than a surface of a rod that rests on the rod support surface.

8. The polyaxial bone anchoring device of claim 6, wherein an angle between the short portion and the long portion is greater in the second configuration than in the first configuration.

9. The polyaxial bone anchoring device of claim 6, wherein the deformable portion of the pressure member comprises at least two upstanding legs extending respectively on either side of the rod support surface.

10. The polyaxial bone anchoring device of claim 6, wherein the rod support surface has a substantially V-shaped cross section in a plane perpendicular to the longitudinal axis.

11. The polyaxial bone anchoring device of claim 1, wherein the locking member is a two-part locking member that comprises a first member configured to engage the receiving part and a second member rotatably connected to the first member, wherein the second member is configured to engage the deformable portion.

12. The polyaxial bone anchoring device of claim 1, wherein when the head and the pressure member are in the receiving part and the deformable portion is in the first configuration, the pressure member clamps the head such that the head is maintained in an angular orientation but is not locked.

13. The polyaxial bone anchoring device of claim 1, wherein the pressure member is a monolithic piece.

14. The polyaxial bone anchoring device of claim 1, wherein the pressure member comprises a main body, the deformable portion comprises at least one separate part connectable to the main body, and the deformable portion has superelastic properties.

15. The polyaxial bone anchoring device of claim 1, wherein the deformable portion is elastically deformable from the first configuration to the second configuration, and in the second configuration, the deformable portion is configured to assume the first configuration when the locking member moves in the channel towards the first end of the receiving part.

16. The polyaxial bone anchoring device of claim 1, wherein the deformable portion remains in the second configuration when the locking member moves in the channel towards the first end of the receiving part.

17. A polyaxial bone anchoring device comprising:
a bone anchoring element comprising a shank for anchoring to a bone and a head;
a receiving part comprising a first end, a second end, a longitudinal axis extending through the first end and the

13

second end, a channel at the first end for receiving a rod, and an accommodation space for pivotably holding the head;

a pressure member configured to be positioned in the receiving part and to exert pressure onto the head to lock the head in the receiving part, the pressure member comprising a pressure exerting surface and a deformable portion, wherein the deformable portion is configured to assume at least a first configuration and a second configuration; and

a locking member configured to be inserted into the channel to move in the channel along the longitudinal axis and to exert a force onto the deformable portion of the pressure member;

wherein when the head is in the receiving part and the deformable portion of the pressure member is in the first configuration, the receiving part is configured to support the deformable portion, and the locking member is moveable towards the head to exert a force on the deformable portion for adjusting the deformable portion from the first configuration to the second configuration; and

wherein when the head is in the receiving part and the deformable portion of the pressure member is in the second configuration, the pressure member exerts a force on the head that locks the head relative to the receiving.

18. A polyaxial bone anchoring device comprising:
a bone anchoring element comprising a shank for anchoring to a bone and a head;

14

a receiving part comprising a first end, a second end, a longitudinal axis extending through the first end and the second end, a channel at the first end for receiving a rod, and an accommodation space for pivotably holding the head;

a pressure member configured to be positioned in the receiving part and to exert pressure onto the head to lock the head in the receiving part, the pressure member comprising a pressure exerting surface and a deformable portion, wherein the deformable portion is configured to assume at least a first configuration and a second configuration; and

a locking member configured to be inserted into the channel to move in the channel along the longitudinal axis and to exert a force onto the deformable portion of the pressure member;

wherein when the head is in the receiving part and the deformable portion of the pressure member is in the first configuration, the receiving part is configured to support the deformable portion, and the locking member is moveable towards the head to exert a force on the deformable portion for adjusting the deformable portion from the first configuration to the second configuration; and

wherein when the head is in the receiving part and the deformable portion of the pressure member is in the second configuration, the pressure member exerts a force on the head that locks the head relative to the receiving part.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 11,576,708 B2
APPLICATION NO. : 16/950723
DATED : February 14, 2023
INVENTOR(S) : Lutz Biedermann et al.

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page

Pg. 2, Column 1, After the Abstract

Delete "18 Claims,"
Insert --17 Claims,--.

In the Claims

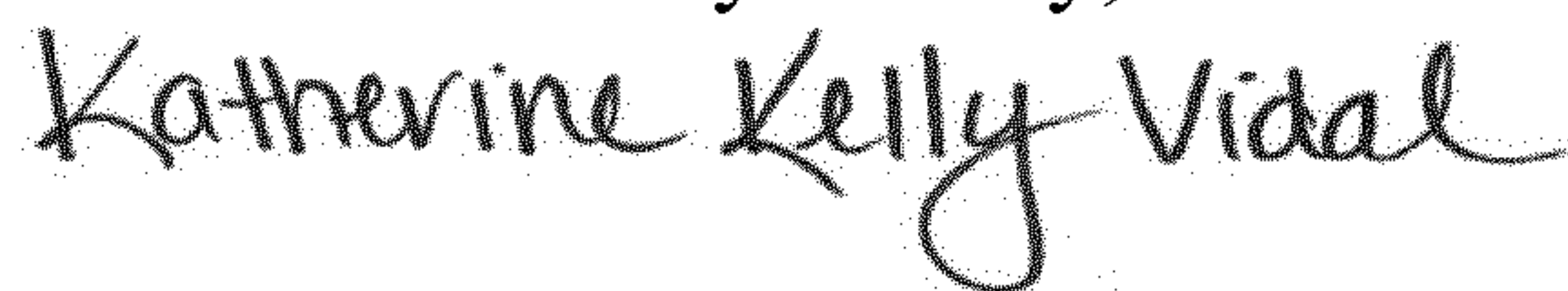
Column 13, Line 27, Claim 17

Delete "receiving."
Insert --receiving part.--.

Column 13, Line 28-30 and
Column 14, Lines 1-29

Delete Claim 18 in its entirety.

Signed and Sealed this
Sixteenth Day of May, 2023



Katherine Kelly Vidal
Director of the United States Patent and Trademark Office